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The biocompatibility of 11 porous canal wall prostheses and 4 dense incus prostheses, both types made of hydroxylapatite, was studied by light microscopy, scanning electron microscopy, transmission electron microscopy, and x-ray microanalysis. The duration of implantation varied between 4 and 40 months, and the 15 retrieved implants constitute 4% of the 375 clinically applied hydroxylapatite prostheses involved in this study. With respect to integration characteristics, coverage by epithelium and fibrous tissue, and biodegradation, the performance of clinically applied hydroxylapatite generally resembled that seen in animal experiments. However, the reactions during chronic infection in the human ear were more severe than those in experimentally induced acute infections in the rat middle ear. One of the canal wall prostheses showed trace element accumulation in the cytoplasm of phagocytes.

KEY WORDS — biocompatibility, cholesteatoma, hydroxylapatite, infection, middle ear prostheses.

INTRODUCTION

The biocompatibility of ceramics currently used in reconstructive middle ear surgery has been assessed in animal experiments by a number of authors,[1-11] and with few exceptions[6] the results seemed favorable for most of the materials. However, despite the many detailed evaluations, extrapolation of the results to humans is still difficult, because although postoperative clinical results have been reported, data on the biocompatibility of applied ceramics are scarce.[1,12,13]

Furthermore, in addition to the difficulty of interpreting the results of studies done in animals because of the lack of sufficient clinical data on biocompatibility, the most frequent cause of failure of otologic implants, ie, infection,[14,15] has only been evaluated for tricalcium phosphate[2,16] and hydroxylapatite,[11,17,18] and not for any of the other ceramics. In view of this lack of data on the biocompatibility of otologic biomaterials in general and their performance during infection in particular, we undertook a study to evaluate the biocompatibility of hydroxylapatite implanted as canal wall and incus prostheses.[19,20] In these series of 375 implanted prostheses, 22 were removed during a second operation for the treatment of chronic otitis media or residual cholesteatoma or for failure due to fixation. The assessment of the biocompatibility of 15 of these prostheses by light microscopy, scanning electron microscopy, transmission electron microscopy, and x-ray microanalysis is reported in this paper.

MATERIALS AND METHODS

Hydroxylapatite Ceramic. Two types of prostheses were investigated: an auditory canal wall prosthesis made of macroporous hydroxylapatite and an incus replacement prosthesis made of dense hydroxylapatite. Details concerning the properties of the ceramic and the prostheses have been published elsewhere.[11]

In total, 15 canal wall prostheses and 7 incus prostheses have been removed, out of a series of 189 canal wall and 186 incus prostheses, representing 5.8% of the total number of implants. In the present study 11 canal wall and 4 incus prostheses were investigated by light microscopy, scanning electron microscopy, transmission electron microscopy, and x-ray microanalysis.

Light Microscopy. Immediately after surgical removal the prostheses were immersed in phosphate-buffered physiologic saline (4°C) and transferred within 2 hours to a glutaraldehyde solution (1.5% in 0.14 mol/L sodium cacodylate, 4°C). After fixation for at least 16 hours, the prostheses were brought into a solution containing 10% EDTA and 1.5% glutaraldehyde (pH 7.4) at room temperature. Decalcification took at least 4 weeks, after which the specimens were dehydrated in an ethanol series and embedded in Paraplast. Sections cut 7 μm thick were stained with hematoxylin and eosin.

Scanning Electron Microscopy. The preparation for scanning electron microscopy was similar to that for light microscopy, except that most of the fragments of the canal wall prostheses were not decalcified. After dehydration, the specimens were critical point dried, mounted on a stub, sputtered with gold, and studied in a Cambridge Stereoscan 180 scanning electron microscope.

Transmission Electron Microscopy. The material intended for transmission electron microscopy was processed as for light microscopy; however, after decalcification it was postfixed in 1% osmium tetroxide, dehydrated, and embedded in Epon. Ultrathin sections mounted on copper grids were stained with lead citrate and uranyl acetate, before being examined in a Philips EM 201 electron microscope.

X-ray Microanalysis. Samples were studied with

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TIME TO REMOVAL OF PROSTHESIS AND REASON FOR REMOVAL

Prosthesis	*Postoperative Interval (mo)*	*Cause of Removal*
Canal wall		
1	29	CSOM (*Proteus mirabilis*)
2	25	CSOM (*Staphylococcus aureus*)
3	40	Residual cholesteatoma
4	4	Fixation failure
5	5	CSOM (*Staphylococcus aureus*)
6	11	CSOM
7	14	CSOM, fixation failure
8	10	CSOM (*Staphylococcus aureus*)
9	11	Residual cholesteatoma
10	21	CSOM
11	8	CSOM
Incus		
1	15	Residual cholesteatoma
2	6	Residual cholesteatoma
3	10	Fixation failure
4	32	CSOM

CSOM — chronic suppurative otitis media.

either a back-scattered electron detector or a scanning transmission electron detector in a Philips EM 400 electron microscope. X-ray microanalytical spot analyses were performed with a Tracor Northern TN 2000 x-ray microanalyzer.

RESULTS

The 11 canal wall and 4 incus prostheses investigated in this study were removed during operations made necessary by chronic suppurative otitis media, residual cholesteatoma, and fixation failure. The reasons for removal and the postoperative interval are shown in the Table. The findings are presented below in three subsections dealing with integration, coverage by epithelium and fibrous tissue, and biodegradation.

INTEGRATION

Interface Characteristics. Light microscopy and transmission electron microscopy showed three tissues near the surface of the canal wall prostheses, namely bone, fibrous tissue, and exudate. The incus prostheses showed predominantly fibrous tissue and some exudative cells (mainly macrophages). Examination of the interface between hydroxylapatite and these tissues by transmission electron microscopy often showed an electron-dense layer (Fig 1). In several instances this layer was continuous with the lamina limitans of bone near canal wall prostheses. In spite of the frequent occurrence of this layer, it was never seen in association with macrophages or multinucleated cells at the hydroxylapatite/tissue interface. Since inactive osteoclasts and foreign body giant cells are hard to distinguish on morphologic grounds, and the calcium phosphate nature of hydroxylapatite makes it impossible to exclude the presence of osteoclasts, the neutral term multinucleated cells is preferred.

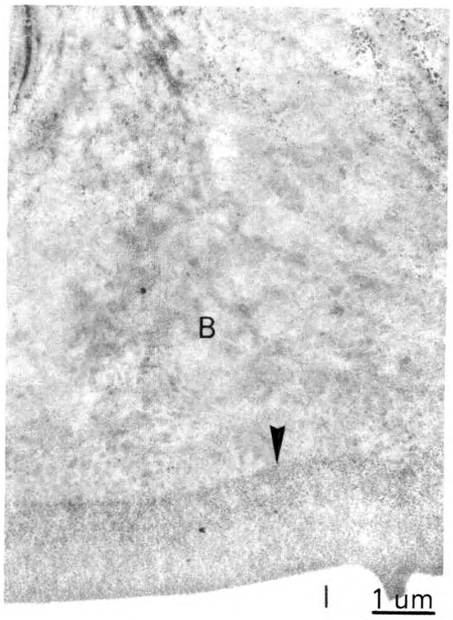

Fig 1. Transmission electron microscopy of electron-dense layer (arrowhead) at hydroxylapatite (I)–bone (B) interface.

In cases with a fracture line running through the ceramic it was of interest that at the encounter with a macropore filled with tissue, the fracture would continue its course equally often through the ceramic, through the tissue, or along the interface. Where the fracture ran along the interface, imprints of the hydroxylapatite granules could be seen in the tissue in the pore, and granules of hydroxylapatite were sometimes found integrated into bone tissue (Fig 2A), which x-ray microanalysis showed to be characterized by a spectrogram with calcium and phosphorus peaks (Fig 2B).

Tissue Ingrowth. Besides the interactions at the hydroxylapatite/tissue interface, ingrowth of tissue into the pores of a canal wall prosthesis contributes to integration. The pores of the canal wall prostheses showed bone and fibrous tissue, but also exudate. The proportions of these three tissues varied widely among prostheses. Some prostheses had the pores filled predominantly with bone and fibrous tissue (Fig 3A), whereas others showed many pores partially or totally filled with exudate (Fig 3B). This exudate was primarily localized at the periphery of the implant, but in a minority of the cases occurred in the center. The number and proportion of exudative cells also differed among prostheses: some pores were filled with transudate, and some macrophages were seen, as well as pores obliterated by polymorphonuclear granulocytes, lymphocytes, plasma cells, macrophages, multinucleated cells, and eosinophils. Where exudate from the middle ear cavity was still attached to the prosthesis, its composition was similar to that of the exudate in the pores. Concerning the presence of fibrous tissue and bone, it can be said that even the prostheses with

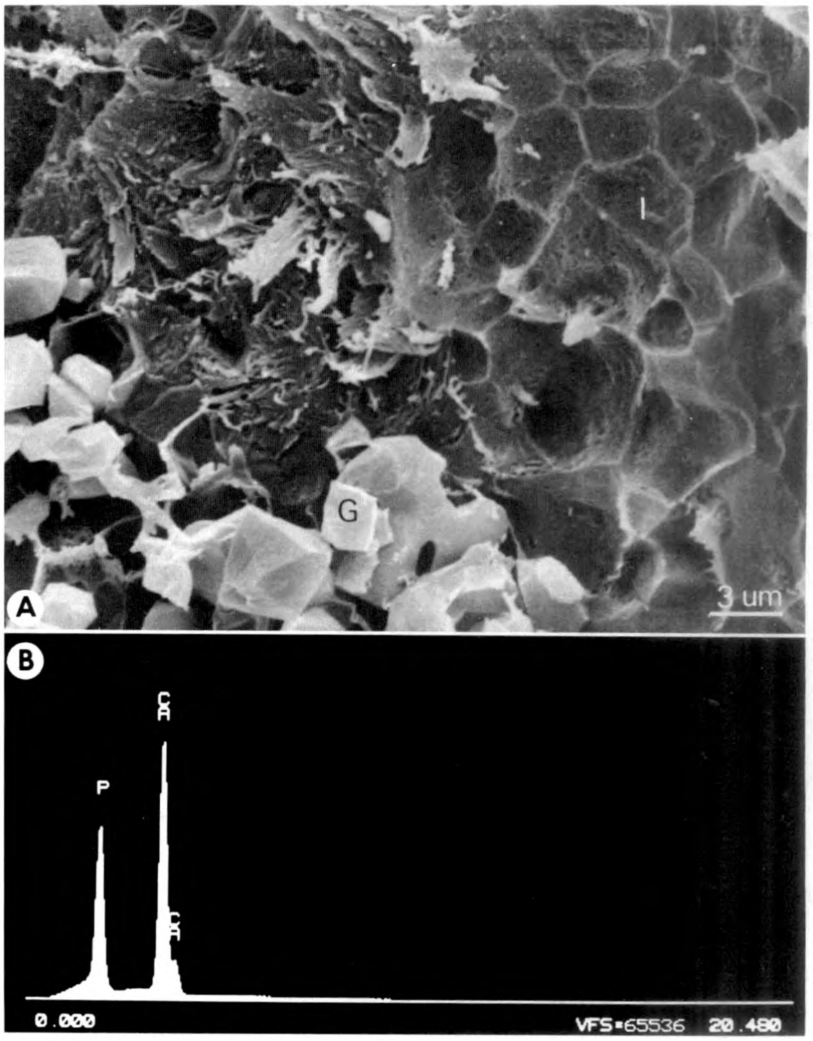

Fig 2. Hydroxylapatite/tissue interface at fracture site. A) Scanning electron micrograph. Note granules (G), impressions in tissue (I), and collagen strands. B) Spectrograph of x-ray microanalysis of granules in A. P — phosphorus, CA — calcium.

relatively large amounts of exudate showed pores completely filled with bone and fibrous tissue. The fibrous tissue was rather similar to that described in Coverage by Epithelium and Fibrous Tissue, below. Bone showed a normal morphology in light and transmission electron microscopy. It was composed of a dense network of collagen fibers, osteoblasts, osteocytes, lacunae, and canaliculae (Fig 4). In general, bone was in direct contact with the pore periphery, but occasionally it was also found at some distance from the hydroxylapatite surface. Pores with peripherally located bone frequently had a central capillary.

COVERAGE BY EPITHELIUM AND FIBROUS TISSUE

Because the removal of canal wall prostheses usually involved severe damage of the covering tissue, such prostheses could not be used for the study of coverage by epithelium and fibrous tissue. This discussion will therefore be confined to the incus prostheses, which were suitable for the purpose despite the partially damaged tissue covering.

Epithelium. Scanning electron microscopy showed flat polygonal epithelial cells on the surface of the tissue covering the prostheses. The number of microvilli on the cell surface varied widely, and some of the cells were heavily covered with these structures (Fig 5A). Transmission electron microscopy confirmed the scanning electron microscopic findings and showed that the cells were generally rather thin and had normal cellular organelles, eg, mitochondria, rough endoplasmic reticulum, and nucleus.

The fibrous tissue that separated the epithelium from the prosthesis varied in thickness and was composed of loosely arranged collagen fibers, fibroblasts (Fig 5B), and capillaries. Although exudative cells were difficult to identify by light microscopy, transmission electron microscopy revealed small numbers of macrophages and multinucleated cells at the hydroxylapatite/tissue interface. Small numbers of macrophages and polymorphonuclear granulocytes were seen incidentally in the fibrous tissue as well.

In one case an incus prosthesis was covered by the matrix of a residual cholesteatoma, and at this site scanning electron microscopy showed no degradation of the prosthesis.

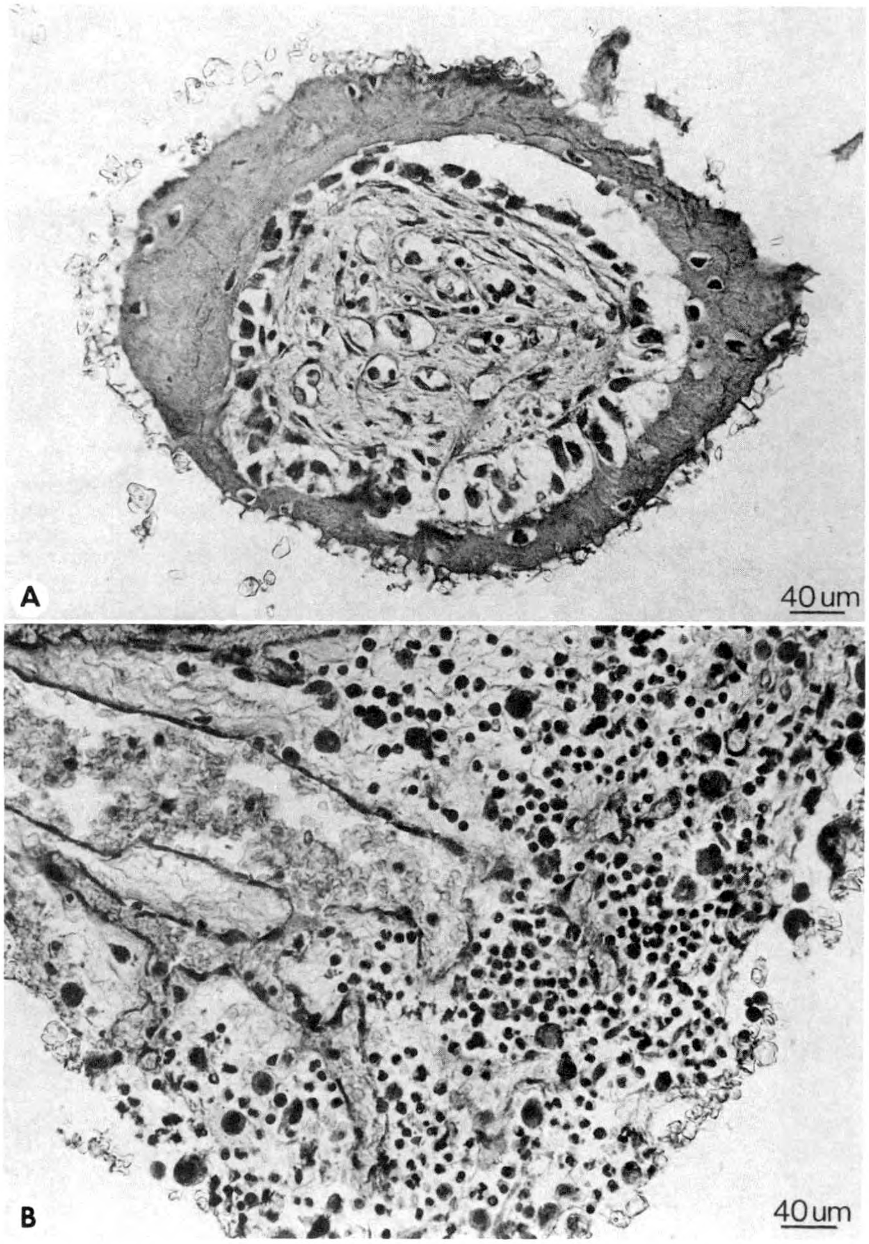

Fig 3. Light micrographs of macropores. A) Filled with bone and fibrous tissue. B) Predominantly filled with exudate.

BIODEGRADATION

In each of the foregoing sections reference was made to the presence of macrophages and multinucleated cells. Transmission electron microscopy showed phagocytized debris, lipid vacuoles, areas with electron-lucent granules, and clefts in the cytoplasm of such cells. These phenomena were also observed for macrophages and multinucleated cells in the middle ear exudate and did not seem to be associated with the prostheses, whereas the presence of rather rectangular electron-dense vacuoles in the cell cytoplasm and vacuoles with similar morphology but without the electron-dense material was characteristically related to an implant. X-ray microanalysis of the electron-dense vacuoles gave high peaks for calcium and phosphorus, indicating the implant-derived origin of these structures. In one case of a canal wall prosthesis removed after 11 months because of residual cholesteatoma, electron-dense inclusion bodies with divergent morphology were seen as well (Fig 6A). Analysis of the contents of these bodies showed peaks of aluminum, silicon, magnesium, titanium, and iron, sometimes in relatively pure fractions (Fig 6B).

Although the presence of implant-derived material in the cytoplasm of mononuclear and multinucleated phagocytes seems indicative of biodegradation, the prostheses seldom showed clear signs of degradation. Usually the implant surface still had the same scaly appearance as before implantation (Fig 7). However, at the hydroxylapatite/tissue interface in pores at the periphery of the implant, light microscopy revealed indentations in the ceramic filled with macrophages and/or multinucleated cells, suggesting a relatively high rate of degradation (Fig 8).

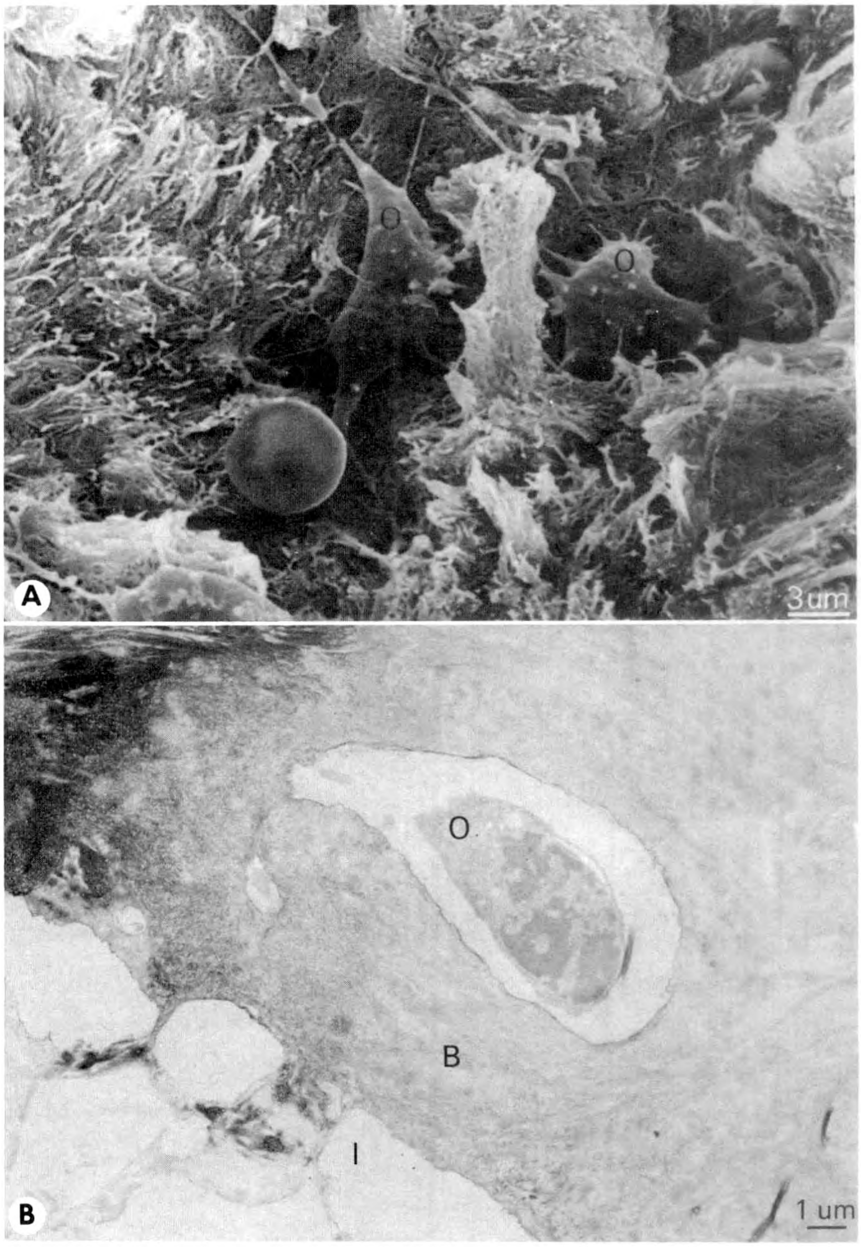

Fig 4. Bone morphology. O — osteocyte. A) Scanning electron micrograph of bone exposed to hydroxylapatite wall of macropore. Collagen strands and osteocytes are visible. B) Hydroxylapatite (I)–bone (B) interface as seen by transmission electron microscopy. Note collagen in calcified matrix under osteocyte.

DISCUSSION

Before the present findings are discussed, it should be pointed out that these 11 canal wall and 4 incus prostheses, made of porous and dense hydroxylapatite, respectively, represented only 4% of 375 implanted prostheses investigated. All of them had been exposed to unfavorable conditions, and therefore these 15 cannot be considered representative of the prostheses that were not removed. Nevertheless, they form a very interesting population, since 86% of the retrieved prostheses had resided in a middle ear cavity affected by chronic suppurative otitis media with cholesteatoma, and both recurrent and residual disease are quite common after mastoidectomy for this disease.[21] This situation means that the evaluation of the biocompatibility of the retrieved prostheses is important in two respects. First, it yields information on the general biocompatibility of hydroxylapatite ceramic in humans, but especially, it provides indications concerning the performance of the ceramic under the conditions of chronic suppurative otitis media and/or residual cholesteatoma.

One of the most characteristic properties of hydroxylapatite ceramic is its ability to form a direct bond with bone at the hydroxylapatite/tissue interface. This bond was reported to be associated with an electron-dense layer at the interface,[22,23] described in both animals and humans.[22,24,25] This layer showed a calcium salt deposit composed at least partially of calcium phosphate, presumably in the form of hydroxylapatite.[23] Thus, epitaxy or continuity between the artificial and biologic hydroxylapatite crystals might explain the bonding osteogenesis at the interface.[26] As in the studies mentioned above, we again found an electron-dense layer at the hydroxylapatite/tissue interface and a

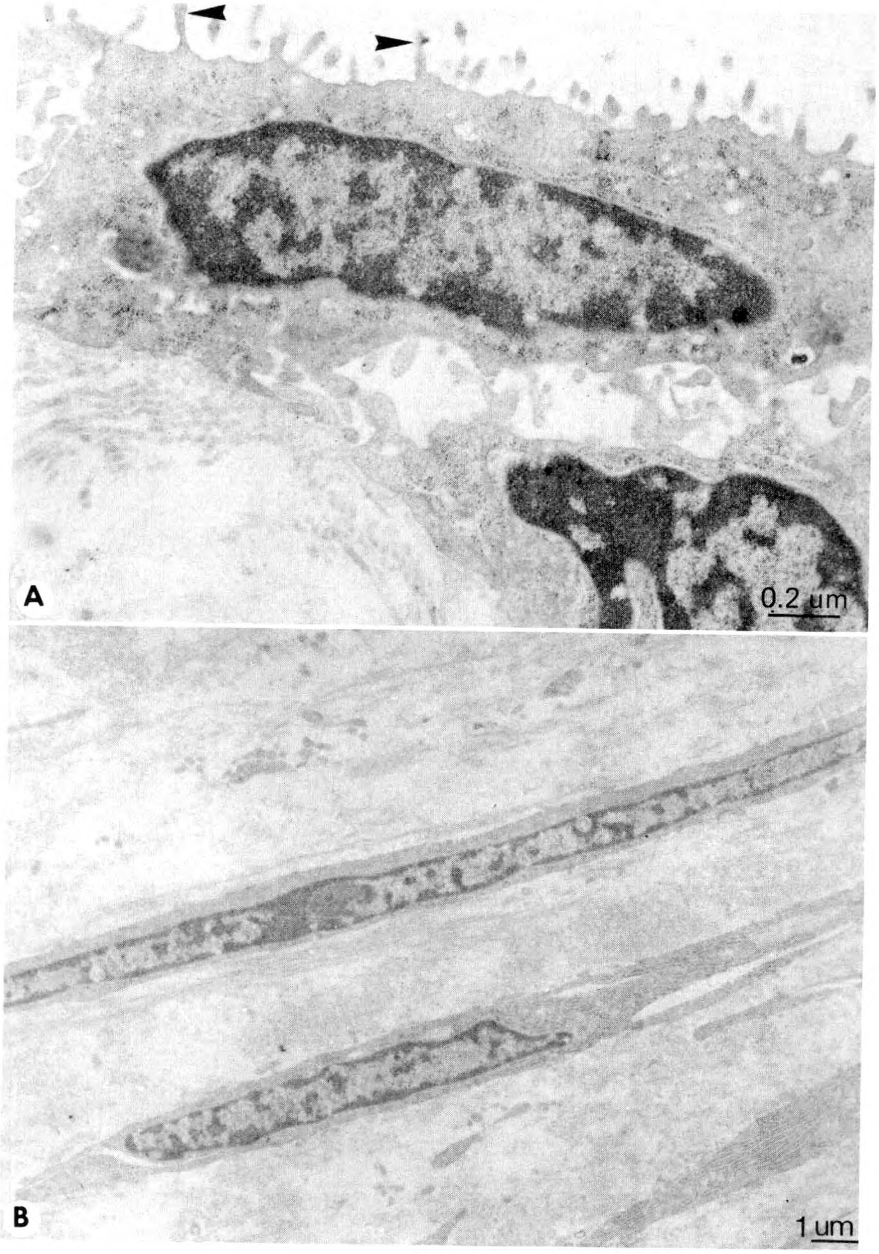

Fig 5. Transmission electron micrographs. A) Epithelium on surface of incus prosthesis. Note abundant microvilli (arrowheads). B) New fibrous tissue covering incus prosthesis. Fibroblasts and randomly oriented collagen fibers are visible.

firm bond at this interface, as demonstrated by the behavior of fracture lines through the implant material, which suggested that the bond at the hydroxylapatite/bone interface is just as strong in bone as in the ceramic. These findings confirm the results of animal experiments in which the behavior at the hydroxylapatite/bone interface was found to be similar in the noninfected middle ear[22] and middle ears experimentally infected with *Staphylococcus aureus*.[17,18]

Another feature of the retrieved canal wall prostheses that corresponded with findings in animals with infected[17,18] and noninfected middle ears[27] was the ingrowth of bone and fibrous tissue into the pores. In some prostheses the pores were predominantly filled with bone and fibrous tissue and contained only minimal exudate. Bone was deposited directly against the periphery of the pore, a mode of bone deposition that may be considered characteristic for biomaterials with bioactivity for bonding with bone, eg, Bioglass,[5] Ceravital,[4] tricalcium phosphate,[2,16] and hydroxylapatite.[22,27] The presence of pores partially or totally filled with exudate was also seen in the infected middle ear of the rat.[17,18] However, in the rat the exudate was confined to pores at the periphery of the implant, while some of the clinically retrieved prostheses also showed exudate in more centrally situated pores. Furthermore, the exudate found in the clinically applied prostheses generally suggested a more severe reaction than the experimental infection in the rat. This divergence can be explained by the fact that the experimental infection was essentially an acute one,[28] whereas the infection in human ears was chronic. Furthermore, the rat might be rela-

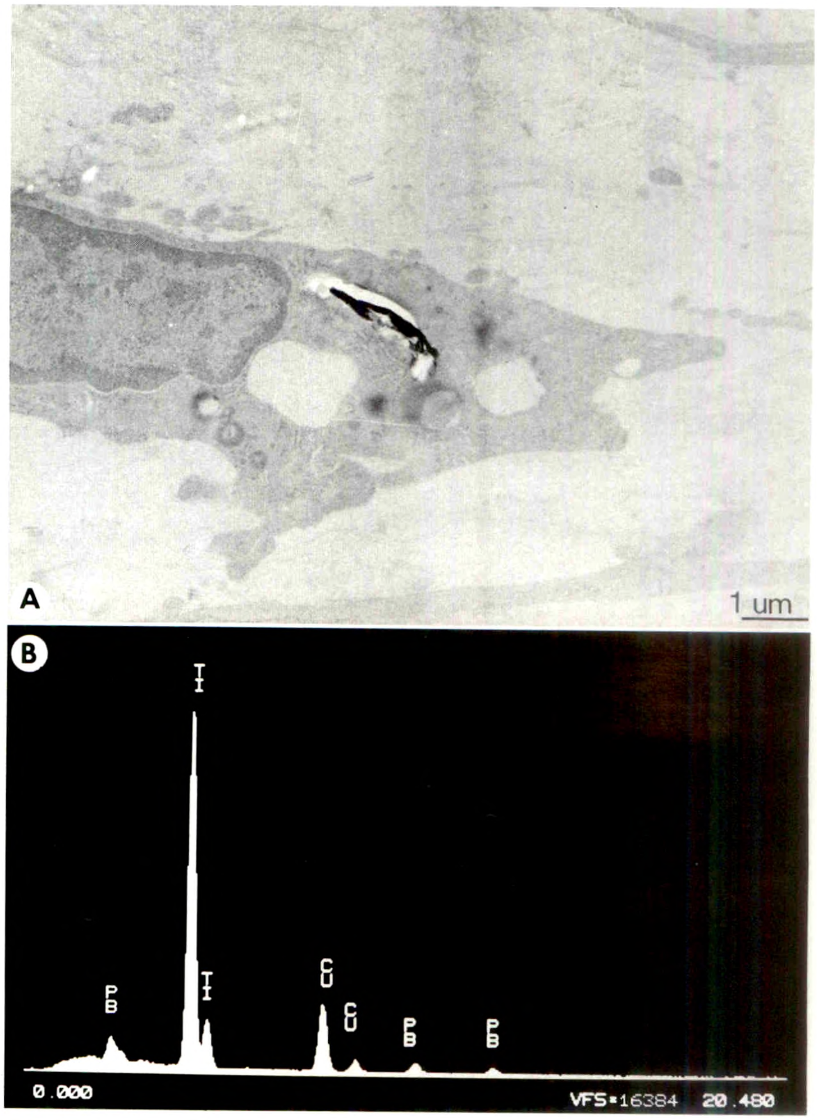

Fig 6. Macrophage in fibrous tissue in macropore. A) Transmission electron micrograph. Note electron-dense inclusion. B) Spectrograph of x-ray microanalysis of electron-dense structure in A. Peak of titanium (TI) can be seen. Peaks of lead (PB) and copper (CU) are caused by preparation procedures.

tively insensitive to infection by *S aureus*,[29] which was associated with the retrieved prostheses in at least three cases. If these assumptions are valid, a model of a more severe, chronic animal infection should be developed as a basis for good biocompatibility evaluation of otologic implants. In spite of the relative insensitivity of the rat to *S aureus*, this pathogen will remain the organism of choice, because it is the one most frequently found with implant-associated infection.[30]

The epithelial cover on the incus prostheses was rather similar to the epithelium of the normal middle ear. This is consistent with earlier studies in animals that only showed clear-cut effects of infection on epithelium during short-term infection.[18,31] The presence of a roughly normal epithelium is not indicative of good biocompatibility, because prostheses characterized by a strong foreign body reaction or even outright toxicity show a normal-looking epithelial layer.[32,33] Rapid covering with epithelium is an important criterion indicating reduction of an implant-associated infection.[34] Unfortunately, the prostheses under discussion had all been in situ for at least 4 months and therefore did not provide any information about the rate at which coverage by epithelium occurs.

Besides the divergent behavior of the retrieved human implants exposed to infection, the biodegradation properties should be mentioned. Opinions differ in the literature on biodegradation, some reports describing degradation[23] and others mentioning no degradation.[35] In the middle ear of the rat, hydroxylapatite degradation was estimated at 15 μm/year on the basis of morphometry.[23] Since morphometry was not included in the present study, an estimation of the rate of degradation cannot be given, but it is clear that degradation must have been limited, because large areas of the implant surface still retained the original scaly structure. Animal studies on the infected middle ear did not indicate an effect of infection on the rate of degradation of hydroxylapatite ceramic.[17,18] However, in the present study some of the exudate-filled pores at the periphery of the implant showed indentations in the

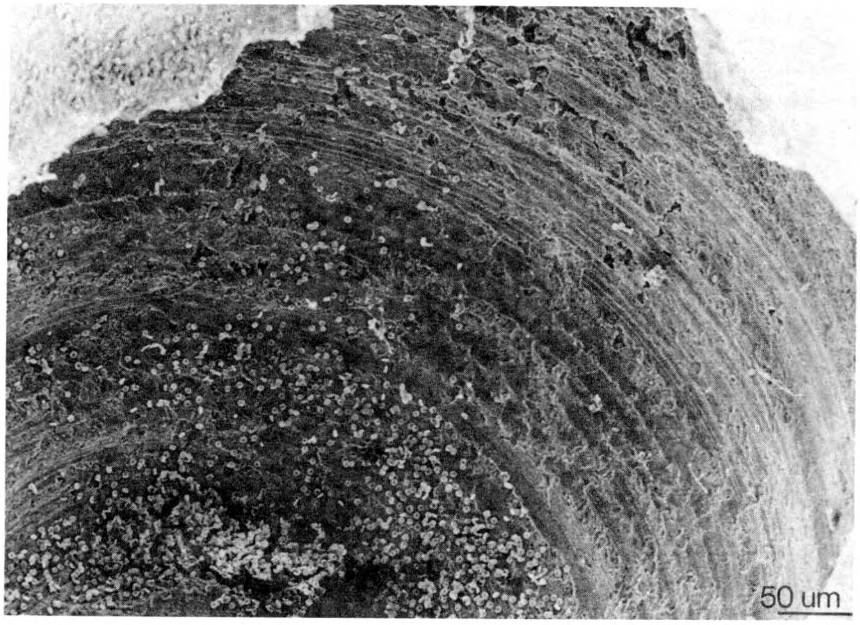

Fig 7. Scanning electron micrograph of niche in incus prosthesis. Because of tissue damage caused by surgical removal, scaly implant surface is visible.

ceramic suggestive of degradation associated with infection. Although this effect was limited, it contrasts with the findings in animals, perhaps because of interspecies differences, but also perhaps because of differences in the severity and duration of the infection.

Also related to biodegradation was the presence of aluminum, silicon, magnesium, and iron in electron-dense inclusion bodies in phagocytes near one of the 15 hydroxylapatite prostheses. Each of these elements had originally been present in concentrations of 0.2% or less in the bulk material before implantation.[36] Such accumulation, ie, of tricalcium phosphate[16] and three polymers,[12] was seen in earlier studies and was postulated to be a general phenomenon associated with biodegradable biomaterials.[12] The fact that this phenomenon has not been seen for hydroxylapatite before, either in animals or in humans, suggests that the presence of cholesteatoma could have played a role.

In general, the results reported here confirm published reports on hydroxylapatite in animals and humans. However, a few discrepancies suggest a slightly divergent behavior of the ceramic during chronic suppurative middle ear infection, residual cholesteatoma, or fixation failure. It may be concluded that although the biocompatibility of hydroxylapatite is affected by chronic middle ear disease, its behavior remains satisfactory even under the unfavorable conditions discussed here.

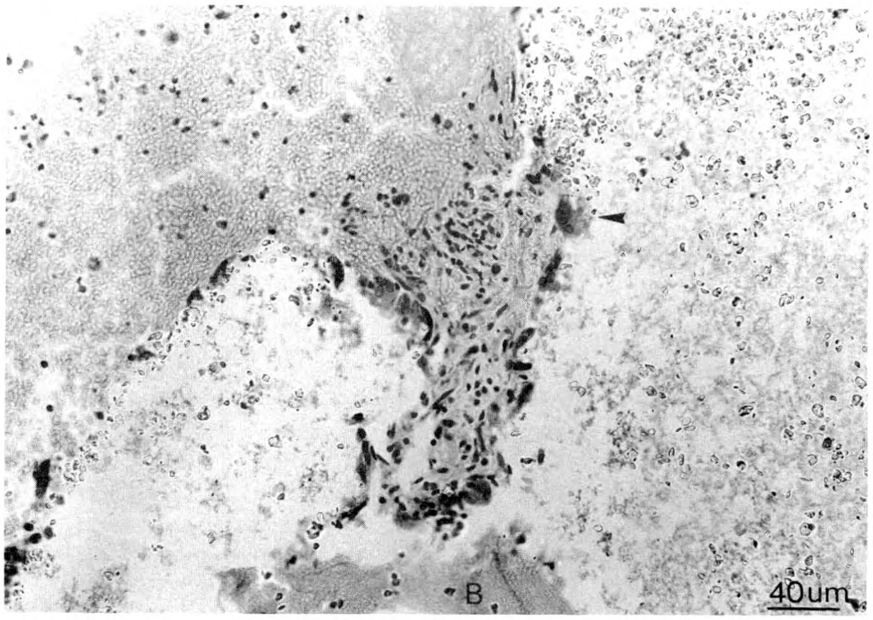

Fig 8. Light micrograph of transition zone between middle ear exudate and hydroxylapatite implant. Exudate and fibrous tissue obliterate pore periphery, whereas bone (B) fills more central part of implant. Note indentations associated with multinucleated cells (arrowhead).

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CALCUTTA

RECONSTRUCTION OF THE MIDDLE EAR WITH HYDROXYLAPATITE IMPLANTS: LONG-TERM RESULTS

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LEIDEN, THE NETHERLANDS

The results are reported of reconstructions of the middle ear with hydroxylapatite implants performed between 1980 and 1986 with an average follow-up of 5 years. The findings concern 120 canal wall prostheses made of hydroxylapatite. It was possible to reconstruct a radical cavity with a new ear canal. The results obtained with ossiculoplasty in 170 patients are reported. In patients lacking an incus, an incus prosthesis made of hydroxylapatite gave air-bone gap closure to within 20 dB in 83.3% of the patients. Extrusion was not observed. In cases with the stapes superstructure and incus both missing, an incus/stapes prosthesis made of hydroxylapatite gave an air-bone gap closure to within 20 dB in 75.7% of the cases, when used as an assembly. Extrusion was not observed. When the prosthesis was used as a columella, the results were less favorable (41.1%), and two prostheses were extruded during the postoperative control period. Recurrent cholesteatoma was not seen in cases in which eradication and reconstruction were staged.

KEY WORDS — cholesteatoma, hydroxylapatite, middle ear prostheses.

INTRODUCTION

Closed techniques for the eradication of cholesteatoma were developed to avoid the problems posed by an open cavity and improve conditions for the reconstruction of a functioning middle ear.[1-3] The availability of hydroxylapatite ceramic middle ear implants means that eradication can be done with an open technique, and if necessary, a new middle ear can be created at a later stage. A small cavity combined with a type 3 tympanoplasty usually gives no problems, and hearing results can be good. If reconstruction of a cavity combined with formation of a new canal wall and reconstruction of the middle ear chain is necessary, use is made of hydroxylapatite implants. Eradication and reconstruction are staged, and reconstruction is only performed after 2 years in cholesteatoma-free cavities.

The indications for the reconstruction of a cavity are

1. Patient wishes to hear better.
2. Patient has recurrent infections of the cavity and wants a dry ear.
3. Patient wants to be able to go swimming without an earplug.
4. Patient needs better canal conformation for fitting of a hearing aid.
5. Patient becomes dizzy if the ear is exposed to wind.
6. Any combination of the above.

The canal wall prosthesis made of porous hydroxylapatite can replace the former bony wall of the ear canal.[4] Both the incus prosthesis and the incus/stapes prosthesis are made of dense hydroxylapatite and eliminate the defect in the ossicular chain in cases with loss of the incus or the stapes superstructure and incus[5] (see Figure; A,B).

Hydroxylapatite is a bioactive ceramic that resembles the mineral matrix of bone. Several studies have shown good compatibility in dry and infected middle ears.[6-8] A direct bond is formed with surrounding tissue. In the middle ear the material behaves as autologous and homologous bone, but has the advantage of being easy to obtain. The porosity of hydroxylapatite is optimal for a controlled remodeling in living bone tissue.

MATERIALS AND METHODS

The canal wall prosthesis is made of porous hydroxylapatite ceramic with the chemical composition $Ca_{10}(PO_4)_6(OH)_2$. The material has a macroporosity of 30% (pore size, approximately 100 μm) and a microporosity of less than 5% (pore size, approximately 3 μm).

This report describes the results obtained in 120 patients in whom a reconstruction of a canal wall was performed in the period between January 1980 and December 1986. In this period 130 cavities were reconstructed. The youngest patient was 10 years old, and the eldest, 63 years. Ten patients failed to keep adequate postoperative appointments, and their data have not been included in the analysis. Follow-up occurred at 1, 3, and 6 months, and after that annually. The average duration of follow-up in this study was 5 years. The shortest postoperative period was 2 years, and the longest was 8 years.

The surgical technique used for the reconstruction of a cavity was a canal wall prosthesis, leaving a wide posterior tympanotomy for aeration of mastoid and middle ear as described elsewhere.[4]

The artificial middle ear ossicles were made of dense hydroxylapatite ceramic. The surface of the implants makes a direct bond with living tissue at the points of contact and is not subject to significant

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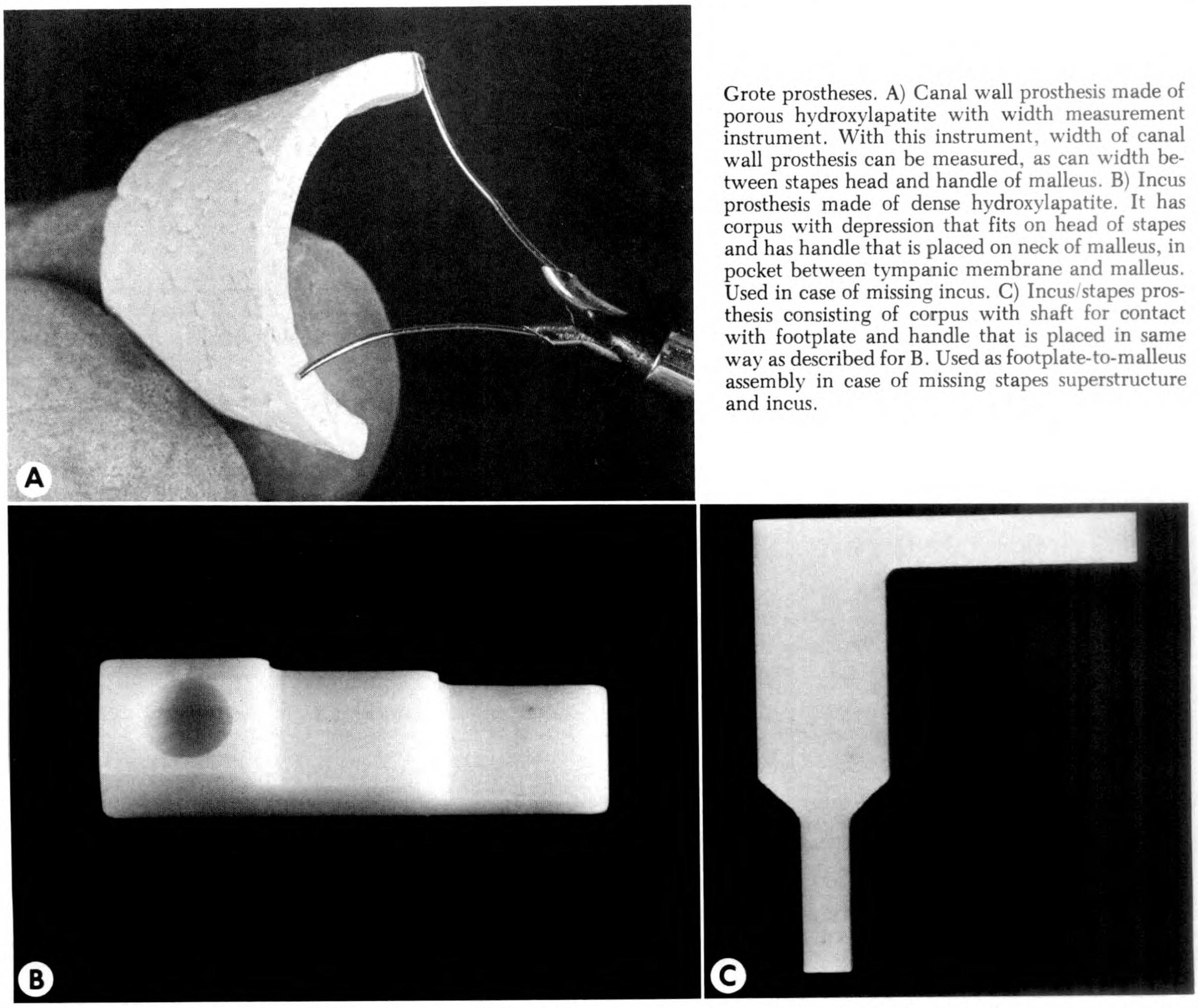

Grote prostheses. A) Canal wall prosthesis made of porous hydroxylapatite with width measurement instrument. With this instrument, width of canal wall prosthesis can be measured, as can width between stapes head and handle of malleus. B) Incus prosthesis made of dense hydroxylapatite. It has corpus with depression that fits on head of stapes and has handle that is placed on neck of malleus, in pocket between tympanic membrane and malleus. Used in case of missing incus. C) Incus/stapes prosthesis consisting of corpus with shaft for contact with footplate and handle that is placed in same way as described for B. Used as footplate-to-malleus assembly in case of missing stapes superstructure and incus.

degradation, even in infected surroundings in the animal.

Of 170 patients, 59 patients with an ossiculoplasty had a canal wall reconstruction in addition. The patients were operated on between January 1980 and December 1986, and the average duration of follow-up was 5 years. The shortest postoperative period was 3 years, and the longest, 8 years. In this period 175 patients were treated, but 5 failed to attend all the follow-up appointments. One hundred twenty of the patients were given an incus prosthesis, 29 having a canal wall reconstruction in addition. This type of prosthesis is used as an assembly between the head of the stapes and the handle of the malleus. The prosthesis consists of a corpus with a depression that fits on the head of the stapes and a handle with three steps that is placed on the handle of the malleus between the tympanic membrane and the neck of the malleus, forming a stable reconstruction of the defect. Fifty patients were given an incus/stapes prosthesis, 30 having a canal wall reconstruction in addition. This type of prosthesis is placed between the mobile footplate and the handle of the malleus, as just mentioned, to form a stable assembly to replace a missing stapes superstructure and incus. The surgical techniques have been described elsewhere.[5]

CANAL WALL RECONSTRUCTION

Preoperative and Operative Findings. In 75 cases the cavity was infected and the ear had continuous otorrhea (Table 1). The patients were treated preoperatively, but 14 of them still had granulation tissue in the mastoid at the time of reconstruction, 48 patients had a perforated tympanic membrane, and 20 had atelectasis of the middle ear cleft. Four patients had a normal ear canal with a cholesteatoma lateral to the middle ear chain; in these cases eradication and reconstruction were performed in the same operation. In 10 patients a residual cholesteatoma was found under the skin lining the mastoidectomy cavity. Despite the rule for staging of reconstruction and eradication, except for limited cholesteatomas, these 10 patients received reconstruction in the same stage as total removal of the residual cholesteatoma.

Postoperative Results in Epithelium and Tympanic Membrane. In 12 patients a postoperative defect was found in the epithelium of the new ear canal. In 5 this defect closed spontaneously within 3 to

TABLE 1. FINDINGS IN 120 PATIENTS WITH CANAL WALL RECONSTRUCTION

	No. of Patients	
	Preoperative & Operative	*Postoperative*
Tympanic membrane perforation	48	14
Otorrhea	75 (C)	16 (R)
Atelectasis of middle ear	20	15
Cholesteatoma (primary, acquired, or recurrent)	4	0
Residual cholesteatoma	10	2

Average control period was 5 years.
C — constant, R — recurrent.

TABLE 2. AIR-BONE GAP CLOSURE AND RATE OF EXTRUSION AFTER OSSICULOPLASTY IN 170 PATIENTS

	Within 20 dB		*Within 10 dB*		*No Improvement*		*Extrusion*	
	No.	*%*	*No.*	*%*	*No.*	*%*	*No.*	*%*
Incus prosthesis (n = 120)	100	83.3	74	61.6	9	7.5	0	0
Incus/stapes prosthesis (n = 50)								
As assembly	25	75.7	14	42.4	6	18.1	0	0
As columella	7	41.1	1	5.8	10	58.8	2	4

Average control period was 5 years.

6 months. The rest of the patients showed a defect in the skin with a very thin layer of flat epithelium. Two patients developed granulation tissue around the defect after swimming. Perforation of the tympanic membrane was present in 14 patients, and 19 showed retraction of the membrane. In 15 patients there was atelectasis of the new middle ear cleft (Table 1).

Infection. Sixteen patients had recurrent otorrhea in the postoperative follow-up period. Of these patients, one had granulation tissue in the middle ear as well as in the mastoid, and required reoperation. Two patients had recurrent infection with granulation tissue in a retraction pocket, which could be controlled by suction and topical medical therapy. Eight patients had an otorrhea only in connection with upper airway infections. Two patients had a period of external otitis, and in three patients the discharge was caused by an infection of a pocket behind the skin of the lateral part of the new ear canal. This pocket was due to an inadequate meatoplasty that left the lateral skin flap in poor contact with the canal wall prosthesis. After surgical correction of the pocket, the new ear canal remained dry.

Cholesteatoma. So far, cholesteatoma has not recurred in the postoperative period. In all cases with a residual cholesteatoma, that is, cholesteatoma left behind at the original operation and reconstruction performed in the same stage, a reinspection was done. In two of these patients the residual cholesteatoma was still present and had eroded the new posterior canal wall.

Removal of Canal Wall Prostheses. Five canal wall prostheses were removed during the follow-up period, two of them because of fracture of the canal wall associated with a head injury. In the first year after the operation the prostheses were replaced by a new canal wall. One removal of a canal wall prosthesis was in a patient with granulation tissue in the mastoid and the middle ear requiring a new cavity. Two prostheses were removed, and a new cavity was created in cases requiring removal of residual cholesteatoma. In all patients in this series the canal wall prostheses were well integrated as well as ossified, and, as would a normal ear canal, they had to be removed with a bur.

OSSICULOPLASTY

Incus Prostheses. One hundred twenty patients with an incus prosthesis were included in this study (Table 2). The air-bone gap was within 20 dB in 100 patients (83.3%), it was within 10 dB in 74 (61.6%), and no improvement was obtained in 9 (7.5%). The results of the ossicular chain reconstruction combined with closure of the tympanic membrane perforation in 31 patients resulted in an air-bone gap within 20 dB in 70.9% and within 10 dB in 51.2%. The combination of an ossiculoplasty with reconstruction of the canal wall in a cavity gave an air-bone gap within 20 dB in 82% and within 10 dB in 55.2%. Spontaneous extrusion of the incus prosthesis has not occurred in the postoperative period. Three prostheses were replaced because of perforation of the tympanic membrane on top of the handle of the malleus at the point of contact between the incus prosthesis and the malleus handle. The prosthesis was too long for the distance between the stapes and the handle of the malleus. The perforation showed no reaction except for the formation of crusts. Of the nine patients without hearing improvement, five were reinspected. Three showed loss of contact with the stapes head, and the area of contact with the malleus handle was fibrous. Two patients showed good fibrous contact with the stapes head, but the function was inadequate because the anterior crus of the stapes was missing. In the follow-up period the hearing gain remained constant.

Incus/Stapes Prostheses. Fifty patients with an incus/stapes prosthesis were included in this study (Table 2). The postoperative air-bone gap was within 20 dB in 32 patients (66%) and within 10 dB in 15 patients (30%). There was no improvement in 16 patients (32%). In this study the incus/stapes prosthesis was used as an assembly between the footplate and the handle of the malleus in 33 patients, whereas in 17 patients a malleus handle was not present and the incus/stapes prosthesis was used as a columella between the footplate and the tympanic membrane. Where the incus/stapes prosthesis was used as an assembly, the air-bone gap was within 20 dB in 25 patients (75.7%) and within 10 dB in 14 patients (42.4%). Six patients (18.1%) showed no improvement. In cases with a columella, 7 patients had an air-bone gap within 20 dB (41.1%), 1 patient came within 10 dB (5.8%), and 10 patients (58.8%) showed no improvement. There was no statistical difference in the results of treatment when the ossiculoplasty was performed in the same operation with or without a myringoplasty or with the reconstruction of the cavity with a hydroxylapatite canal wall prosthesis. During the follow-up period none of the incus/stapes prostheses used as an assembly was extruded, whereas two incus/stapes prostheses were extruded when used as a columella. Extrusion was due to retraction of the tympanic membrane around the columella. No inflammatory reaction occurred if the membrane was in contact with the ossicular prosthesis made of hydroxylapatite. The hearing gain was constant in all patients during the follow-up period.

DISCUSSION

From the present results it is clear that the open technique does not guarantee removal of the cholesteatoma in all cases. In 10 cavities thought to be freed of residual cholesteatoma, a cholesteatoma was later found behind a normal skin lining.

In 83% of the cases the need for hearing improvement was the indication for reconstruction of the cavity. The success of an ossiculoplasty intraoperatively in a modified radical operation is uncertain, and this has been one of the reasons for the choice of the closed technique. An intact middle ear cavity can also be achieved with a hydroxylapatite canal wall prosthesis. Although atelectasis of the new middle ear cleft occurred, a well-aerated middle ear and mastoid could be obtained in a majority of the cases. As indicated, for good results it is essential that sufficient skin lining be available for the new ear canal and the tympanic membrane. Of the 75 patients with chronic infection of the cavity, 16 had a recurrent otorrhea after the reconstruction, and 5 of these cases could be corrected. Eight of the patients had only an otorrhea in connection with an acute upper airway infection. In 3 patients the infection could be eliminated by a second operation in which the pocket between the new canal wall and skin was corrected. The new ear canals were self-cleaning, and the patients with a closed tympanic membrane were allowed to swim.

In eight cases a combined hearing loss was the indication for reconstruction of a new ear canal to fit a hearing aid, which can be a problem in a cavity. There were no extrusion problems with the hydroxylapatite canal wall prostheses. This is not surprising, because hydroxylapatite resembles the mineral matrix of living bone tissue, and its performance has been studied long-term in vitro and in animal experiments. Even in infected surroundings, this ceramic has proven to be a good implant material, behaving like bone, and resorption and remodeling are controlled.[4-8]

Postoperative biopsy and biologic assessment of the removed hydroxylapatite prostheses have shown that remodeling occurs as in living bone tissue. Reconstruction of the posterior auditory canal wall with ventilation of the mastoid, as in this study, has also been achieved with autologous and homologous preserved cartilage and bone,[2,3,9] but postoperative resorption is often seen. The use of plastic implant materials such as Proplast and Plastipore has not been successful in the long run. Materials such as tricalcium phosphate and glass ceramics have been used for the posterior canal wall. Tricalcium phosphate (β-whitlockite) is a controversial material with regard to remodeling.[10] Glass ceramics are also bioactive with respect to bone bonding,[11] but these prostheses are not porous and are not remodeled into living bone tissue.

Although in 19 patients a retraction pocket developed and in 15 patients atelectasis of the middle ear occurred, no recurrent cholesteatoma was observed during the given follow-up period. Follow-up will continue. An explanation of why recurrent cholesteatoma has not been seen so far may lie in the fact that the reconstruction was done by design only in cholesteatoma-free cases.

The new external ear canal was wide, and the lateral epitympanic annular area was closed off by the prosthesis, which meant that retraction pockets anterior and posterior could be controlled. The new bony annulus of the middle ear was placed more laterally. Another essential element of the technique is the use of Gelfilm as sheeting that extends from the mastoid through a very wide posterior tympanotomy to the eustachian tube.

It is not known how long the period between eradication and reconstruction should be, because the pathogenesis of cholesteatoma is not yet understood. In our series reconstruction was performed 2 years after eradication.

The results obtained with the hydroxylapatite ossicles are comparable to those seen with autologous or homologous ossicles. When used as an assembly, the connection between the prosthesis and the handle of the malleus and head of the stapes prevents extrusion. A potential problem with sculptured autograft and homograft ossicles is postoperative resorption, especially if an infection develops.[12,13] Deterioration of hearing was not observed in this study with hydroxylapatite ossicles, indicating that there was no significant degree of postoperative resorption. In cases with a missing incus, use has also been made of a partial ossicular prosthesis or short columella made of plastic implant material. The use of porous plastic implant materials such as Proplast and Plastipore has been advocated as giving better integration,[14] but longer follow-up periods are associated with an increasing rate of extrusion. The insertion of cartilage between such prostheses and the tympanic membrane may prevent these extrusions, but with hydroxylapatite no interface is necessary between the prosthesis and the membrane, as shown by the present study.

When the stapes superstructure and an incus are missing but a mobile footplate and handle of malleus are present, a total ossicular prosthesis or long columella reaching from the footplate to the tympanic membrane is usually used.[15] Lateralization may be one of the problems encountered with a columella. An assembly prosthesis has the advantage of securing the new middle ear ossicle between the remnants of the ossicular chain, which provides a lasting result, as this study shows.

Placement of the handle of the prosthesis in the pocket between the tympanic membrane and the neck of the malleus gives good stability. According to Austin's[15] report on the results of a malleus-to-footplate assembly made of an autograft or homograft incus, the average hearing gain was 22.9 dB, the major cause of failure being fixation of the prosthesis. In our study no postoperative deterioration of the hearing gain was observed in the postoperative period.

Brackmann and Sheehy[14] showed 55% air-bone gap closure within 10 dB and 84% within 20 dB with the use of a TORP of Plastipore, but in their study the postoperative follow-up period was 6 months. The hearing results we obtained with the incus/stapes prosthesis made of hydroxylapatite are comparable with these results. When the prosthesis was used as a malleus-to-footplate assembly, extrusion was not seen in this longer postoperative study.

The selection of patients for ossicular reconstruction is important. In all cases of cholesteatoma, eradication and reconstruction were staged. In cases with a purulent discharge, preoperative treatment was given so the operation could be done with as much healthy epithelium as possible.

The long-term results with these hydroxylapatite implants indicate that it is possible to reconstruct a normal middle ear with lasting hearing results. This means that the eradication can be done with an open technique. For patients with a totally empty middle ear and absence of the handle of the malleus, studies to find new solutions are in progress.

SUMMARY

This study indicates that hydroxylapatite, as the mineral matrix of bone, is an ideal implant material for reconstruction of the posterior canal wall and defects in the middle ear chain. With staging of eradication and reconstruction, so far no recurrent cholesteatomata were observed. Extrusion of the hydroxylapatite middle ear ossicles was not observed when they were used as an assembly between footplate and malleus or stapes and malleus.

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DANISH APPROACH TO THE TREATMENT OF SECRETORY OTITIS MEDIA

REPORT OF THE DANISH CONSENSUS CONFERENCE COPENHAGEN, 1987

Editors
CHRISTIAN BRAHE PEDERSEN, MD
JORN OLSEN, MD

ANNALS
OF OTOLOGY,
RHINOLOGY &
LARYNGOLOGY

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The conference was planned by a working group appointed by the Committee on Health Research and Medical Technology Assessment of the Danish Medical Research Council, consisting of Per Buch Andreasen, Jorn Olsen, Christian Brahe Pedersen, Henning Poulsen, Anders Thylstrup, and Niels Tygstrup. Secretarial duties were undertaken by Torben Jorgensen and Annette Thomas of the Danish Hospital Institute. The report was translated into English by Helen Jean Cribb and Roberta Hansen, and its original layout was done by Lone Danner and Christian Brahe Pedersen.

Additional copies of this publication are available from Christian Brahe Pedersen, MD, ENT Department, Århus University Hospital, 8000 Århus, Denmark, or may be purchased from Annals Publishing Company, 4507 Laclede Ave, St Louis, MO 63108.

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PREFACE

In cooperation with the Danish Hospital Institute, the Danish Medical Research Council held a Consensus Conference in Copenhagen from March 30 to April 1, 1987. The topic under discussion in the Fourth Consensus Conference was "Treatment and Prevention of Secretory Otitis Media."

It was the responsibility of the Consensus Conference Panel to answer the following questions:

1. What are the most important causes of secretory otitis media (SOM), and how widespread is the disease?
2. How is a diagnosis of SOM arrived at, and what diagnostic methods are available for establishing the degree of severity?
3. What methods of treatment are available for patients suffering from SOM?
4. What are the developmental consequences for a child suffering from periodic loss of hearing?
5. What are the advantages and disadvantages of intubation, both long-term and short-term?
6. What are the psychological, organizational, and economic consequences of different methods of treatment of SOM?
7. Can SOM be prevented, and what kind of research in this area would be desirable?

It was the responsibility of the Fourth Consensus Conference to discuss problems arising from the treatment and prevention of a frequently occurring complaint, namely that of fluid in the middle ear. This is a condition to which the great majority of children are subject at one time or another during childhood.

In the 1950s and 1960s, equipment to measure the pressure in the middle ear was developed, and from the 1950s intubation of the middle ear gave good results. In a quite simple surgical procedure, a tube was inserted into the eardrum, thereby normalizing the pressure in the middle ear and permitting the child to regain normal hearing immediately. Intubation of the middle ear — one of the possible treatments of SOM — became very popular, and at present 25,000 to 30,000 intubations are carried out yearly in Denmark.

It was the objective of the Consensus Conference to evaluate the specialized medical basis for the methods of treatment frequently used in cases of SOM. In addition, an evaluation of whether the advantages of the various methods of treatment are indicated and efficacious when compared to both economic expenditure and potential disadvantages of treatment was also needed. Thus, the Panel's task was not only to evaluate strategies of treatment, but also to estimate the possibility of prevention.

As in earlier Consensus Conferences, *the Panel was composed of non-experts in the area*. Their task was to evaluate expert testimony and, given the information that had been offered, to formulate concrete proposals for action with reference to the interests of both society and patients. This report was written by the Panel entirely from this point of view.

In the following, short summaries of the experts' statements precede the answers from the Panel.

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ETIOLOGY AND PREVALENCE OF SECRETORY OTITIS MEDIA

DANISH MEDICAL SERVICE

Jorn Olsen, MD

Denmark covers an area of 44,000 square kilometers, has a population of about 5 million people, and is located in the northern part of Europe as a part of Scandinavia and the European Economic Community.

Health care is considered to be of public concern and responsibility, and the financing of the vast majority of health care services is based upon general taxation. The responsibility for providing health services is shared among three levels of government: the national government, the counties, and the municipalities. Most hospitals are now run by the counties and the city of Copenhagen. Physicians working in the primary health care system (general practitioners or specialists) also receive payment from the local counties.

For most patients the general practitioner is the first contact with the health care system, and general practitioners may treat the patients themselves or refer them to the hospital or to specialists working within the primary health care system. In Denmark, general practitioners do not take part in hospital treatment. There are about 15,000 physicians in Denmark (one per 350 or 400 people); 25% work as general practitioners, 61% work at the hospitals, and the rest work in other fields.

INTRODUCTION AND DESCRIPTION OF THE EXTENT OF THE PROBLEM

Christian Brahe Pedersen, MD

The disease secretory otitis media (SOM) has been recognized for more than 100 years. The illness was difficult to diagnose with the equipment available in the past, and this is most likely why the disease has been called by so many different terms. Black[1] states that all in all, more than 55 different terms have been used to describe this illness. The term secretory otitis media was first introduced in 1927. The many different terms reflect the attitudes of the different times as to the cause of the disease and the most important symptoms.

For more than 75 years Danish physicians have been able to read about SOM, but under a different term, namely chronic middle ear inflammation. The illness is described in detail in Schmiegelow's[2] textbook of 1912. For a long time the illness went relatively unnoticed, presumably because of its moderate symptoms. The course of the disease is slow, and there was little interest in the minor problems in children's health and development at the beginning of the century. This is especially the case in comparison with acute middle ear infection, in which the symptoms are more pronounced: the child cries, there is pain, and the ear is draining. By contrast, SOM is a quiet, slowly developing disease.

In medical and technologic development one finds a chronologic coincidence in important diagnostic and therapeutic modalities. An apparatus to measure middle ear pressure was developed in the 1950s and 1960s. Simultaneously, use of the operating microscope became more common and made it possible to see the more discrete changes in the eardrum. The new treatment method that was developed was the ventilation tube, an older invention that Armstrong[3] reintroduced in the 1950s. Suitable materials were not available earlier.

It is this combination of improved diagnostic equipment together with a possibility of effective treatment that has increased the interest in SOM and the treatment of the disease. Furthermore, general prosperity, which includes good social conditions allowing for better medical treatment and interest in children's welfare, has played a role. The earlier treatment methods for SOM were ineffective, but when intubation was introduced whereby a hearing loss could be eliminated with a procedure that takes only a few minutes, it was only natural for such a procedure to become very popular.

The number of treatments for SOM has increased substantially over a 10-year period. Approximately 35,000 intubations are performed yearly in Denmark, mostly on children. Consequently, intubation of the eardrum can be regarded as one of the most commonly performed operations in this country, and it is natural that such a development arouses interest in the public sector, which ultimately is responsible for treatment of illness in Denmark.

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In recent years scientific research has produced results that show that even though intubation immediately solves a problem — in other words, restores normal middle ear pressure and thereby normalizes hearing — the treatment, like any other treatment, still has its complications. If we fail to intubate children, then they will have a hearing loss for a longer or shorter period, with particular consequences if it occurs during an important developmental period in the child's life. Furthermore, some patients suffer permanent damage. If, however, we do intubate, the problem of hearing loss is resolved immediately and some complications are avoided, but the disease is not cured and there may be other complications. The problem is complex and the otolaryngologist's role is to evaluate who should be treated and when.

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CAUSES OF THE DISEASE

Mirko Tos, MD

The causes of secretory otitis media (SOM) are often multifactorial: one etiologic factor initiates the disease process, a second maintains it, and a third aggravates it.

Tos and colleagues have followed three groups of healthy children from birth through school age and have correlated changes in middle ear pressure while simultaneously precisely registering the different etiologic factors.[1,2] The most important etiologic factor causing SOM is upper respiratory tract infections, particularly common colds.[3-6] A significant connection between the presence and frequency of or the severity of colds and the incidence of SOM or dysfunction of the eustachian tube is found for all three groups and for all age groups. The effects of upper respiratory tract infections on the middle ear are different[7]:

1. Upper respiratory tract infections cause nasal blockage and reduced ventilation of the nasopharynx, which also results in reduced ventilation of the middle ear and negative middle ear pressure.
2. Reduced airflow through the nasopharynx produces mucus accumulation in the nasopharynx, which can promote infection of the eustachian tube's mucous membrane.
3. Inflammation of mucous membranes and the resulting hypersecretion of mucus in the nose and nasopharynx is found with upper respiratory tract infections. The inflammation is localized to the mucous membrane of the eustachian tube and results in internal tubal occlusion.
4. With upper respiratory tract infections the lymphatic tissue swells in the nasopharynx, and in children the adenoids can temporarily obstruct the nasopharynx, as these are often enlarged to begin with.
5. The secretion stasis in the nasopharynx and eustachian tube permits an ascending bacterial infection of the middle ear mucous membrane.

It has been demonstrated that children in infant day-care programs have more bouts of secretory otitis than children cared for at home or in private day-care with a maximum number of five children together. The possibility of mutual infection with colds is greater in infant day-care programs than with home care.[1]

Acute suppurative otitis is an important etiologic factor, but it is not the most dominant.[2] The close correlation of SOM with acute otitis can to a great degree be attributed to the fact that acute otitis often is the result of secretory otitis. Furthermore, a close correlation is demonstrated between acute suppurative otitis and catarrh.

Enlarged adenoids are also an etiologic factor of secretory otitis.[7] The adenoids reduce the ventilation through the nasopharynx, increase the stasis of the secretions in the nasopharynx, and are a growing medium for pathogenic bacteria, which prevent the opening of the eustachian tube and, in some cases, can directly block it.

Other etiologic factors are pathogenic flora, especially pneumococci.

Allergies, genetic predisposition, and childhood diseases were not found to be etiologic factors causing secretory otitis.

It has been shown that children who live in modern concrete high-rise apartments have more frequent secretory otitis than those who live in the older residential areas and single-family houses or villas.

In Copenhagen we found no difference in the frequency of secretory otitis in those who live in the well-to-do northern municipalities versus those who live in the southwestern municipalities.

Increased incidence of secretory otitis is found among children in day-care centers with a poor indoor climate who also have parents who smoke.

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FREQUENCY AND COURSE OF THE DISEASE

Mogens Fiellau-Nikolajsen, MD

As recently as 10 years ago, there was a lack of answers to essential questions concerning this common childhood disease, such as

1. How widespread is secretory otitis media (SOM) among children, especially young children?
2. What is the course of the disease if left untreated?
3. Which factors are the most important for the development of SOM?

The required data can only be collected by meticulously following large groups of normal children with regular examinations for many years. Such projects are resource-demanding and run into many practical and theoretic problems. These so-called cohort studies were initiated in 1976 and 1977 (by Danish researchers), and many similar projects have been performed all over the world.

The results from these have been in agreement to a surprising degree, regardless of the racial, climatic, geographic, and methodologic differences. The main findings among these tens of thousands of investigated children are the following.

Serous otitis media does not occur in newborns, and is relatively uncommon during the first 4 to 6 months of life. In the 6- to 12-month age group there is such an explosive increase in the number of new cases that 13% to 15% of all children have SOM around 12 months of age. The frequency of SOM, all factors being equal, peaks at ages 2 to 4 years, during which 20% of all "normal" children have SOM. Another essential finding is the tremendous variability of the middle ear condition, in that one cannot base much on a single examination: 40% to 60% of all children change either for the better or for the worse between each checkup without treatment and regardless of whether there are days, weeks, months, or years between these examinations. Variability and transience make it difficult to characterize the spontaneous (untreated) course of SOM, and the "average duration" of 4 to 6 months for the disclosed cases of SOM found among 3-year-old children tells very little about the nature of the disease. It is more fitting to talk about several spontaneous courses of SOM that are typical: approximately 15% of children have a single episode or a few short episodes (1 to 3 months); approximately 25% have repeated, short episodes; approximately 15% have one longer episode or a few longer episodes (3 to 9 months); approximately 15% have repeated, long-lasting episodes; and finally, approximately 10% have extremely prolonged episodes (1 or more years).[1]

This is what we know about the incidence and spontaneous course of SOM in children. In which respects do children afflicted with SOM differ from others? First and foremost, it is known that these children to a great extent have more colds and suffer from both more frequent episodes and longer ones. The relationship partially explains why SOM is more common and has a longer course 1) in the winter, 2) in children in day-care institutions, 3) in children residing in public housing, 4) in children with allergies (SOM is not an allergic disease), 5) in boys, and 6) in certain families.

The importance of socioeconomic factors is not as great; likewise, reports regarding parents' smoking habits and air pollution (land/city zones) are conflicting. Children with many acute middle ear infections have a greater incidence of SOM, but the consequences and effects vary from case to case.

Even though we possess quite solid knowledge about the general characteristics of SOM, its onset, and spontaneous course — even that it sometimes results in extensive, permanent damage to the middle ear — we are still unable to predict whether a 9-month-old child with SOM, for example, will be cured on his or her own within a short period of time, or whether he or she will be hearing-impaired for years and eventually have a persisting hearing loss later requiring extensive surgical intervention.

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CONSENSUS: WHAT ARE THE MOST IMPORTANT CAUSES OF SECRETORY OTITIS MEDIA, AND HOW WIDESPREAD IS THE DISEASE?

A number of follow-up investigations carried out in Denmark have shown that secretory otitis media (SOM) is one of the most frequent childhood diseases. Only a small minority of children — probably 10% to 20% — will escape suffering from SOM once or more during the course of childhood. Secretory otitis media, therefore, occurs frequently enough to be regarded as one of the normal childhood sicknesses. We do not know with any degree of certainty whether the disease was less or more widespread in earlier times.

Since SOM ranges from nearly normal conditions to marked changes in the middle ear, it is difficult to undertake comparative investigations. It can be very difficult to draw the line between diseased and normal conditions. The incidence rates of the disease reach their peak for children between the ages of 2 and 5. The disease is rare in adults. In the great majority of cases, SOM is a benign disease that will disappear spontaneously within a short period of time. Examination of Danish children has shown that

1. Approximately 15% experience a single occurrence of the disease lasting for 1 to 3 months.
2. Approximately 25% experience multiple occurrences of the disease lasting for 1 to 3 months.
3. Approximately 15% experience a single occurrence of the disease lasting for 3 to 9 months.
4. Approximately 15% experience multiple occurrences of the disease lasting for 3 to 9 months.
5. Approximately 10% suffer from the disease for even longer periods of time (often several years).

To ensure normal hearing, the pressure in the middle ear must be the same as ambient pressure. The pressure is kept at a normal level by the passage of air through the eustachian tube to the middle ear. It is the action of swallowing that under normal conditions will open the eustachian tube.

Secretory otitis media develops via several mechanisms. Infections may cause edema in the mucous membrane, which blocks the eustachian tube and thereby alters the self-cleaning functions of the middle ear and increases the risk of infection. In the presence of infection the number of mucus-producing cells in the middle ear will increase. The increased quantity of liquid thus produced affects the movement of the eardrum, and hearing is consequently reduced.

The only fact known for certain about the cause of SOM is that the risk of getting the disease is increased by repeated infections of the upper respiratory tract. Thus, causes of respiratory infections are also causes of SOM.

SYMPTOMS AND DIAGNOSIS OF SECRETORY OTITIS MEDIA

SYMPTOMS AND DIAGNOSTIC METHODS

Jorgen Sederberg-Olsen, MD

Symptoms. Symptoms can be categorized as early or advanced. An important early symptom is fullness or a direct feeling of pain coming from the ear. Typically, an infant will awaken after having been asleep for a couple of hours and pull at the ears. Another early symptom is hearing loss. This may be observed by the parents, the public health nurse, the general practitioner, or a preschool program.

Preschools recruit quite a few young patients with hearing losses that are revealed in relation to retarded speech development. The subsequent otologic evaluation often reveals a hearing loss of around 30 dB, which is the amount created by the sealing of the ear canal with a wax (cerumen) plug.[1] Advanced symptoms can manifest themselves in abnormal behavior patterns and retarded development. Adjustment difficulties can be expressed by a degree of withdrawal.[2] Children can appear to be understimulated. When they are unable to participate in their playmates' games, psychological problems can develop with aggression, and personality development can be affected by both retarded speech development and reduced acoustic memory.[3,4]

Advanced anatomic changes are atrophy of the eardrum, as well as eardrum collapse and perhaps cholesteatoma formation.

Diagnostic Methods. The case history can provide reasons for suspicion of fluid in the middle ear. Fluid in the middle ear is often found with the continuation of a cold. Children in day-care nurseries and preschool programs constitute a group at great risk. Acute middle ear infections are also accompanied by fluid in the middle ear. There will be fluid in the middle ear 1 month later in approximately one third of the children with acute middle ear infections.[5]

The diagnosis is made by otoscopy, eventually supplemented with pneumatic otoscopy (Siegle's otoscope), in which by means of small pumping movements one can get an impression of the eardrum's mobility, and whether there is an accumulation of fluid or not.

With use of the otomicroscope the specialist can make a far better evaluation of the eardrum's condition, including mobility. Furthermore, at the specialist's office tympanometry is performed, which registers the conditions of mobility within the middle ear, measured by the eardrum's acoustic impedance.[6] One obtains a measurement for pressure in the middle ear, and the pressure will always be reduced with secretory otitis media. The examination is diagnostically quite exact, painless, and reproducible, and can be documented by the plotting of tympanograms.[7] Finally, with older children the hearing is evaluated by means of pure-tone audiometry.

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DEGREE OF SEVERITY

Jan Steglich-Petersen, MD

As is the case with all other diseases, the degree of severity of secretory otitis media (SOM) is determined by the case history together with the results from some objective evaluations.

The case history is crucial in SOM when one has the evaluation results at hand and has to decide if treatment should be initiated and how it should be done, or whether one should observe the patient for a period of time without treatment and, if so, for how long. The mildest and therefore also the most difficult cases of middle ear fluid (effusion) to diagnose are the cases in which the parents have not suspected a hearing impairment and in which there has not been evidence of recurring ear pain. Usually these cases are in children between the ages of 0 and 5 years who seem constantly to have a common cold. It becomes easier when the parents themselves suspect a hearing impairment in their child. The children with middle ear fluid who have often had episodes with ear pain have usually taken some type of antibiotic several times before they come to an otolaryngologist for the first time. The number of antibiotic treatments contributes to the picture of the degree of severity of the disease. The number of earlier intubations sheds light on it also.

Throughout the years there has been a certain tendency to emphasize the examination results at the expense of the history. Two children of the same age can react completely differently with the same hearing impairment, depending upon their temperament, presence of siblings or playmates, and day-care in an institution. Evaluation of the degree of severity of the disease ought to include the following.

Tympanic Membrane Microscopy. The advantages of using a microscope for examination of the eardrum are its strong light source and its magnification, which make it easier to see possible air bubbles or the fluid line in the middle ear behind the eardrum. With the most difficult cases one will see a very retracted, thin tympanic membrane that is adherent to the ossicles.

Examination of Eardrum's Mobility. The more reduced the eardrum's mobility is, the more likely there is disease present.

Measurements of Middle Ear Pressure. If the pressure in the middle ear is less than 400 mm H_2O or even lower, it is an indication of an almost blocked eustachian tube, and the middle ear will often be filled with fluid. If the pressure is between 0 and 100 mm H_2O, as a rule there will be ventilation of the middle ear.

Different Methods of Hearing Evaluation. It is important to get an impression of the hearing acuity and preferably a quantitative measure of the degree of severity of a possible hearing impairment. The examination of a child's hearing by means of whispering from different distances from the ear is an imprecise method. Audiometry is much better, because it can be performed in a soundproof booth. Among the children we intubate, hearing thresholds are usually found in the area of 25 to 35 dB hearing level, which means that it can be difficult to follow a conversation among several people and that in the school classroom the child can have difficulty hearing what classmates say. Children under 3½ or 4 years most often cannot be tested by conventional audiometry, but several methods are available that can give an impression of whether there is a hearing loss or not.

ROLE OF THE GENERAL PRACTITIONER IN DIAGNOSIS

Erling Kjaerulff, MD

In the following, the methods of evaluation usually employed by the general practitioner (GP) will be reviewed. The methods include use of Siegle's otoscope, an instrument that can change the pressure in the ear canal so that movement of the tympanic membrane can be evaluated. This instrument is available in every GP's consultation room.

Another possible method for estimating the patient's hearing is a tuning fork test. As the name indicates, only a tuning fork is necessary, and the investigation is simple to perform. In some GPs' practices, audiometric equipment for measuring hearing and a tympanometer to measure middle ear pressure are available.

Preventive pediatric checkups are available for all children from birth to the age of 5, and this opportunity is used by approximately 90% of all parents. At preventive pediatric checkups, otoscopy and estimation of the hearing are performed. At the 5-year checkup the child's hearing is evaluated by audiometry; the National Board of Health has recommended this examination.

Investigation into the incidence of secretory otitis media (SOM) in the preventive pediatric checkup group of children has shown an incidence of SOM equal to that mentioned in the literature. It has been shown that SOM often follows diseases like the common cold and especially acute middle ear infection. Investigations from GPs have shown that patients with acute upper and lower respiratory tract diseases account for approximately 10% of all consultations, and for the country as a whole the GP will see a great number of patients with suspicion of SOM.

Otoscopy is included in the routine examination of a child with a fever or upper respiratory tract infection, which allows for detection of fluid in the middle ear during the acute infection episode. It is generally accepted that children with middle ear changes are offered follow-up checkups some time after the acute disease and are followed until the ears have normalized. Recommendations for how long children with SOM should be followed by the GP before referral to an otolaryngologist are not unequivocal, and large individual differences in GPs' practices do exist. The waiting period before referral to the otolaryngologist naturally is dependent on the GP's expectations of the effect of continuous treatment, including the necessity of insertion of ventilation tubes.

It is assumed that GPs with their present routine will be able to identify patients with SOM and be able to take care of follow-up of this disease when spontaneous recovery is expected or otherwise give medical treatment. The most urgent questions that have to be clarified are when the GP should refer the patient to the otolaryngologist and when is the optimal time for intubation. If these questions could be clarified, more consistent follow-up examinations in general practice could be performed.

CONSENSUS: HOW IS A DIAGNOSIS OF SECRETORY OTITIS MEDIA ARRIVED AT, AND WHAT DIAGNOSTIC METHODS ARE AVAILABLE FOR ESTABLISHING THE DEGREE OF SEVERITY?

A diagnosis of secretory otitis media is arrived at partly on the basis of the symptoms of the disease, and partly on the basis of clinical investigation. The most frequent symptoms are hearing loss, feelings of fullness in the ear, and possible alterations in behavior. In a clinical investigation, otoscopy permits the eardrum to be scrutinized. The eardrum will be retracted concavely because of low pressure in the middle ear, and sometimes a liquid reflection can be seen behind the eardrum.

By use of pneumatic otoscopy (Siegle's otoscope), it can be observed that the movement of the eardrum is reduced when pressure in the external auditory canal is altered. With the tuning fork test, a conductive loss of hearing of 25 dB or more can be registered. The pressure in the middle ear can be directly measured by impedance audiometry, a procedure that can be used to establish four degrees of severity as follows. Type A is the normal condition. Pressure in the middle ear is +50 to −99 mm H_2O. In type C1, the pressure is −100 to −199 mm H_2O. In type C2, the pressure is −200 to −400 mm H_2O. In type B, pressure measurements show that the eardrum does not alter its acoustic resistance. Type B is therefore the most serious condition.

An atrophic (thin) eardrum can make impedance audiometry difficult to interpret; and the test is unusable if the eardrum is perforated. Audiometry is used to investigate the hearing. Generally speaking, the more fluid in the middle ear, the worse the child's hearing will be. Finally, alterations in the eardrum can be examined under magnification with an otomicroscope.

Some of the measurements cited are subject to a certain degree of variation, partly because of fluctuations in the manifestations of the disease, and partly because of uncertainty in the measurement procedure itself.

TREATMENT OF SECRETORY OTITIS MEDIA

METHODS OF TREATMENT AVAILABLE

Torben Lildholdt, MD

Establishing the diagnosis of secretory otitis media is the first step in treatment. The child's everyday life must be adapted to the present hearing loss. It is especially important that the child's parents do not react aggressively to the child's behavioral changes. The high rate of spontaneous recovery must be explained to the parents, but at the same time the importance of regular control must be stressed.

Nonsurgical treatment includes mechanical and medical intervention. Mechanical treatment consists of air's being blown into the middle ear (inflation) through the eustachian tube. By use of autoinflation, the nose and mouth are closed with forced expiration, increasing upper airway pressure. By politzerization, upper airway pressure is increased through the nose with control of the pressure when possible. Politzerization has been used in a great number of patients and is still used. Although there are no investigations of the therapeutic effect of this treatment, a new investigation of the composition of the air in a normal middle ear indicates an adverse effect of politzerization.[1] This has been documented in animal experiments with apes.[2]

Medical treatment can be local or systemic. Nosedrops or sprays can reduce the edema of the mucosa caused by upper airway infection, which is often present at the same time. It is expected that the passage from the nasopharynx to the middle ear is improved at the same time, but no scientific proof exists.[3]

Systemic treatment includes mucolytics, corticosteroids, and decongestants plus antihistamines (to reduce edema of the mucosa and allergic reaction). The mucolytics theoretically are attractive and have only minor side effects, but it has been difficult to prove the clinical effect. There is reasonable proof that the other two groups do not show any clinical effect.[4]

Because of the suspicion of low-grade infection in the middle ear and often-present colds, the use of antibiotics is obvious. In the United States this treatment seems widespread in the use of different broad-spectrum antibiotics. There is reasonable documentation of the effect, but recurrence after the treatment usually occurs, as is also the general opinion in this country.

Surgical treatment includes adenoidectomy, paracentesis, and insertion of ventilation tubes. In rare cases, middle ear operation may be necessary. Adenoidectomy originally was described by the Dane Wilhelm Meyer, who reported the hearing improvement obtained more than 100 years ago. In the meantime this connection has been investigated. At present most data suggest or support the theory of Wilhelm Meyer that hearing might be improved following adenoidectomy.[5]

Paracentesis with removal of the mucus in the middle ear is the most simple, basic treatment. The problem is that the incision in the eardrum will close within hours and thereafter the fluid will reappear. This type of treatment can be justified in the time of observation before ventilation tubes are inserted. Paracentesis can be performed with light anesthesia.

Ventilation tubes made from different types of plastic materials or metal are placed in the incision in order to maintain an opening in the eardrum. The initial effect is most often dramatic, with elimination of the subjective inconvenience and with normalization of the hearing. After the introduction of the modern ventilation tubes 30 years ago, attempts have been made to compare the advantages and disadvantages of this type of treatment.[6]

Scientific documentation of the effect of the different principles of treatment is still incomplete. It seems to be most urgent to investigate if instead of the ventilation tube, children could be treated symptomatically, for instance with a hearing aid and analgesics.

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CONSENSUS: WHAT METHODS OF TREATMENT ARE AVAILABLE FOR PATIENTS SUFFERING FROM SECRETORY OTITIS MEDIA?

Since secretory otitis media (SOM) may often be cured spontaneously, one of the clinical options is simply to let the disease follow its own course.

The methods of treatment available to physician and patient can be characterized as follows: mechanical ventilation, medical treatment, and surgical treatment. It is also the case that a temporary loss of hearing can be eased by use of a hearing aid; but this is a method of treatment that the Panel cannot recommend in ordinary cases of SOM.

In terms of symptomatic treatment of SOM, one attempts to increase the pressure in the middle ear and remove the fluid that has accumulated. If this type of treatment is successful, the child's hearing will be normalized.

In mechanical ventilation, the doctor will try to pass air through the eustachian tube into the middle ear — by Valsalva's method, for example, which involves forcing air through the eustachian tube and into the middle ear by strongly exhaling while both nose and mouth are closed off. Somewhat older children can do this for themselves. With smaller children, air can be blown through the eustachian tube into the middle ear via the nose (Politzer's method) when the patient is in the act of swallowing.

The medical treatment of SOM is partly local, partly systemic. Local treatment using nose drops or nose sprays is an attempt to reduce mucous edema in the eustachian tube. Systemic treatment involves an attempt to make the secretions in the middle ear more fluid (mucolytics), or to reduce the mucous edema (by steroid or antihistamine treatment), or to prevent the growth of bacteria in the fluid in the middle ear (by antibiotic treatment). However, to what degree these different types of medical treatment are of benefit has not as yet been fully explored.

Surgical treatment of SOM involves passing air into the middle ear by making an incision in the eardrum (paracentesis), after which the liquid may be suctioned out. The short-term result of this treatment may be prolonged by inserting a plastic tube in the eardrum (intubation). The tube itself, about 2 mm in diameter and about 3 mm long, is placed anteriorly, between the upper and lower quadrants of the eardrum. The operation is carried out with general anesthesia. Sometimes blockading tissue of the nasopharynx is removed at the same time (adenoidectomy), although removal can also be an alternative, independent treatment of SOM. The tubes most commonly used are extruded in about 5 to 10 months.

EFFECT OF HEARING LOSS ON CHILD DEVELOPMENT

DEVELOPMENTAL CONSEQUENCES OF HEARING LOSS IN CHILDREN WITH SECRETORY OTITIS MEDIA

Jorgen Lous, MD

A large number of investigators have shown that severe to moderate hearing loss has an important impact on linguistic and intellectual development and on social adjustment. Therefore, it is reasonable to believe also that mild hearing loss caused by secretory otitis media (SOM) has a negative effect on the linguistic, intellectual, and social development of children. Hearing loss due to SOM is difficult to characterize in a simple way, but most often it will be between 20 and 30 dB — somewhat less in cases of short duration and more severe in cases of long duration. Now and then, normal hearing can be observed even though a pronounced SOM is present.

A review of the published investigations and surveys has been performed in spite of difficulties in comparison due to differences in design, testing, and observation time. A comparison has been made and is shown in the Table.[1-48]

The articles have all been published in English within the last 25 years. Some papers are related to the sequelae of mild sensorineural hearing loss. Ventry[35] in 1980 and Paradise and Rogers[36] in 1980 presented two excellent reviews. Seven of the 13 descriptive studies[1-13] were published before 1980. Most often they describe conditions in a group of patients who had been referred because of linguistic or learning problems or because of SOM. Eleven of the 13 papers found a combination of SOM and learning problems more often than expected.

There were 11 case control studies, of which the 4 oldest[14-17] could demonstrate a connection between SOM and retarded development, while the 4 most recent studies[21-24] could not show any relationship.

In the 10 cohort investigations[25-34] there was a tendency to show a connection between SOM and reduced linguistic development in the older works,[25-27] with no certain relationship in the more recent ones,[28-31,33,34] except for the investigation made by Silva et al[32] in Dunedin, New Zealand.

Among the reviews[35-44] there was a tendency for those authors who stressed the importance of a high scientific standard to feel that there was no positive relationship between SOM and retarded development, while the less critical authors had the opinion that a relationship existed.

The most interesting papers are the newer cohort studies[28-34] in which the details of the method have been described. In looking at this group of papers it is important to realize that in all the studies some cases of long-lasting SOM had been treated.

In the investigation by Teele et al,[28] a large group of children were followed with more than 20 otologic evaluations from birth to 3 years of age. More than 200 children with different frequencies of occurrence of SOM were evaluated with seven different linguistic tests. It was found that the different frequency of occurrence of SOM in the first 3 years of life in the statistical analysis could explain 2% to 5% of the variation in the three tests (understanding of words, receptive language, expressive language), while there was no relationship to the other four tests (IQ, articulation, transformation, length of sentence). The article focused on the relationships established and not on the four tests in which no statistically significant correlation was found.

In the study of Silva et al,[32] 1,000 children were followed from birth to the age of 11 with a large number of investigations including linguistic tests at ages 3, 5, 7, 9, and 11 years. Results of these tests were compared with the otologic findings in children at the age of 5. There was a 15-dB difference in hearing level between the SOM group and the control group. The investigation showed retarded development in verbal comprehension and expression in the SOM group. The size of the difference between the groups is difficult to extract from the paper. The difference is surprising, because classification of the cases and controls is based on only one otologic investigation of children at the age of 5.

In a cohort study from Denmark[31] almost 400 pupils were followed from 7 to 14 years of age. At the beginning of school there was a small correlation between present SOM and speech expression. A number of background factors were investigated. In

LITERATURE ABOUT SECRETORY OTITIS MEDIA AND DEVELOPMENT

		Effect of Secretory Otitis Media on Development		
Type of Study	*No.*	*Yes*	*Uncertain*	*No*
Descriptive studies[1-13]	13	11	0	2
Case control studies[14-24]	11	4	3	4
Cohort studies[25-34]	10	4	2	4
Reviews[35-44]	10	3	1	6
Letters, comments, other[45-48]	4	0	0	4
Totals	48	22	6	20

the statistical model, SOM could explain 2% of the variation, while the other investigative factors could explain 12% to 13%. The most important factor was the social group of the mother, explaining 5% of the variation.

In three well-documented recently published cohort investigations,[30,33,34] no correlation was found between SOM and development. Results in most of the present investigations to date might be influenced by the fact that long-term SOM has been treated during the investigation period.

The few papers presenting the long-term effect of SOM on development in normal children indicate that an eventually slight reduction in development ends when SOM disappears and hearing returns to normal.[22,32] We still do not know if this also is true for children with other handicaps. It is important to stress that the relationship shown between SOM and retarded development in some of the mentioned papers does not necessarily indicate that SOM is the reason for the retarded development.

Some of the present literature indicates that there might be a marginal and brief relationship between SOM and retarded development in otherwise normal children, but clear scientific proof is not yet present. More multidisciplinary research on this very important subject is necessary before it is possible to evaluate the importance of SOM in child development.

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CONSENSUS: WHAT ARE THE DEVELOPMENTAL CONSEQUENCES FOR A CHILD SUFFERING FROM PERIODIC LOSS OF HEARING?

One of the frequent consequences of secretory otitis media (SOM) is a hearing loss. This loss is difficult to characterize unambiguously, since among other factors, it tends in many cases to vary from day to day. It can be stated, however, that it can reach 45 dB. Usually the reduction in hearing is less severe in short-term attacks of the disease, and more severe in long-term occurrences. Occasionally, nearly normal hearing can be registered despite definite SOM.

When children experience a small or fluctuating hearing loss over short or long periods of time, it is common that people in their surroundings — parents, for example, or day-care institution staff — observe alterations in the child's normal pattern of behavior. The child may become withdrawn or aggressive; his or her language development may be retarded. These observations are one of the reasons for the child's being referred for medical investigation and possible treatment.

Investigations indicate a short-term and marginal connection between SOM and reduced language development in normal children during the acute phase of the disease.

A Danish study of children with and without the disease showed a minor variation in language pronunciation. Only in a trifling number of children with SOM could faulty pronunciation be explained because of the presence of the disease, while other background factors were seen as having greater significance.

In our opinion, therefore, the short-term reduction in hearing involved in SOM does not in itself indicate the necessity of surgical intervention.

However, it must be stressed that if parents, day-care institution staff, and others were provided with information about SOM, they would be able to react to the child's temporary reduction of hearing more adequately. Since a loss of hearing is most often under 30 dB and short-term, the child's disability could be relieved by consciously closer contact — among other things, by holding the child in one's arms and speaking directly into his or her ear.

Those few studies on the long-term effect of SOM on the development of normal children indicate that any slight retardation of development that may have occurred will be overcome once the disease has disappeared and full hearing is restored. We do not know as yet whether this is also valid for children with other handicaps.

It is important to emphasize that a proven connection between SOM and retarded development does not necessarily mean that SOM is the cause of the retarded development. We know that a child's development, including linguistic development, is dependent upon numerous social, psychological, and environmental factors, including periods of illness with or without loss of hearing.

In this connection it would also be essential to distinguish those children who are already burdened by excessive illness such as repeated colds — including SOM — so that the effect of social conditions upon these children's development may be examined in more depth. The term "social conditions" refers specifically to conditions in the home, the type of day-care institution attended by the child, and the number of hours spent there.

In conclusion, we lack documentation on the possible long-term developmental consequences of a reduction in hearing caused by SOM. We also lack a more precise description of and investigation into the short-term behavioral and linguistic consequences arising from a reduction in hearing.

Such investigations ought to be cooperatively undertaken by, first and foremost, general practitioners, and by health visitors, psychologists, teachers, parents, and otologists.

SEQUELAE OF OTITIS MEDIA WITH AND WITHOUT TREATMENT

SEQUELAE OF SECRETORY OTITIS MEDIA AND THE RELATIONSHIP TO CHRONIC SUPPURATIVE OTITIS MEDIA

Mirko Tos, MD

The sequelae of secretory otitis media (SOM) are 1) changes in the eardrum,[1-4] 2) changes in the process of pneumatization of the mastoid air cell system, 3) changes in the mucosa of the middle ear, and 4) changes in the inner ear. As the changes in the tympanic membrane are the most important factors for developing chronic suppurative otitis media later in life, this subject will be discussed here.

In the analysis of three of our cohorts of healthy children,[1,2] we have demonstrated that at least 80% of children will have one episode of SOM. Of these periods 15% will be short-term and 25% short-term but recurrent, not causing tympanic membrane sequelae. Fifteen percent of children will have prolonged and another 15% will have prolonged recurrent cases of SOM. Finally, 10% will have exceptionally prolonged SOM. The last-mentioned groups will have sequelae of the tympanic membrane; these can be categorized as changes related to the pars flaccida (attic retraction) and changes in the pars tensa of the tympanic membrane.

In the cohort of healthy children we found, on the average at the age of 5, retraction in the attic to various degrees in 18% of the ears. At the age of 10 attic retraction was found in 26% of the cases.[2] Even though most of the retraction was harmless, we did find severe and deep retraction in 5% of the ears, retraction that later can develop into attic cholesteatoma. In clinical records, 10 to 16 years after treatment of SOM with adenoidectomy and insertion of ventilation tubes a large attic retraction was found in 8% of the ears, and 1% already had developed attic cholesteatoma. In another set of clinical records, 11 to 18 years after treatment corresponding percentages of 6% and 2% were found.

Changes of the pars tensa of the tympanic membrane were found among otherwise healthy 5-year-old children in 9%, and at the age of 10 years changes were found in 18% of the ears. In clinical records changes in the pars tensa of the tympanic membrane following treatment of SOM were found in 58% of the ears, 10 to 16 years and 11 to 18 years later (see Table).

The most important change in the pars tensa is atrophy, in which the tympanic membrane has become thin and has lost all elasticity. The tympanic membrane in the posterior part can retract to such a degree that contact with the stapes is obtained and fixation with retraction pockets develops, which can progress to adhesive otitis or to chronic suppurative otitis media with cholesteatoma. In the thin, atrophic parts of the tympanic membrane, perforation can develop, and chronic suppurative otitis media can develop at a later date. Severe changes in the pars tensa (atrophy with fixation, adhesive otitis, perforation) were found in the 5-year-old group in 1%, in the 10-year-old group in 3%, and in the clinical group in 7% and 16% (see Table).

Tympanosclerosis is a calcification and consequent stiffening of the tympanic membrane. Tympanosclerosis develops especially in children in whom intubation has been performed.[5]

It can be concluded that prolonged SOM is responsible for atrophic changes of the tympanic membrane that increase the risk of further progression into chronic suppurative otitis media. Changes in the tympanic membrane are also the cause of some hearing defects that later in life, especially in combination with presbycusis, may handicap the patient.

INCIDENCE OF CHANGES IN PARS TENSA AFTER SECRETORY OTITIS MEDIA

	Healthy Cohort (% of Children)		*Clinical Group (% of Children)*		
	5 Years Old (N = 444)	*10 Years Old (N = 470)*	*3-8 Years After Treatment (N = 527)*	*10-16 Years After Treatment (N = 362)*	*11-18 Years After Treatment (N = 178)*
Atrophy	2.5	8.1	21.3	14.4	14.6
Atrophy and fixation	0.7	2.3	3.2	4.7	10.1
Adhesive otitis	0.0	0.0	2.5	2.2	3.9
Sinus cholesteatoma	0.0	0.0	0.0	0.3	0.0
Perforation	0.2	0.2	0.0	0.0	1.7
Atrophy and tympanosclerosis	0.7	2.3	9.1	10.8	9.6
Tympanosclerosis	4.7	5.1	18.8	25.7	18.5
Totals	8.8	18.0	54.9	58.1	58.4

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ADVANTAGES AND DISADVANTAGES OF TREATMENT OVER A SHORT OBSERVATION TIME

Agnete Parving, MD

In this description of advantages and disadvantages of treatment with ventilation tubes over a short period of time, I will base the discussion on three different groups of children:

1. Children with congenital or early acquired symmetric hearing loss in which the hearing defect is localized to the inner ear and in which the child has a complicating secretory otitis media (SOM).
2. Children with unilateral deafness and complicating SOM.
3. Children with congenital cleft palate and SOM.

Group 1. Children with congenital or early acquired hearing defects have the same incidence of SOM as other children. If the child has a previously existing hearing loss due to inner ear disease, the SOM will aggravate the hearing loss. It is, among other things, the reason that we perform repeated follow-up evaluations of hearing in these children. The immediate advantage of treatment of SOM with ventilation tubes in these hearing-impaired children is that the child's residual hearing status is restored immediately. Unfortunately, the disadvantage of treating hearing-impaired children with hearing aids is that they risk an infection in the middle ear when the ear canal is closed by an earmold. By experience we know that many of these children who have a ventilation tube inserted and who use a hearing aid will at the same time start developing a purulent otitis media. With modern hearing aids one can increase the amplification of the hearing aid during the period of SOM and thereby avoid the ear discharge that might appear after intubation. The strategy of treatment of hearing-impaired children with complicating SOM is individual and depends on the previously existing hearing loss.

Group 2. Children with unilateral deafness are totally dependent on their only hearing ear. If the child develops a SOM in the only hearing ear, a conductive hearing loss between 30 and 50 dB hearing level can develop that will disturb the child's ability to communicate. Some children react by changing their behavior, and in some cases become aggressive, and in such cases a ventilation tube should be placed in the only hearing ear to normalize the hearing of the child. Disadvantages of treatment with ventilation tubes are the tendency to extrude the ventilation tube with recurrence of SOM and drainage from the ear.

Group 3. Children with congenital cleft palate often show hearing problems due to SOM. Over a long observation time the children also may develop a cholesteatoma that accelerates the otologic problems. Children with cleft palate and prolonged changes in the middle ear can be treated with a hearing aid. Insertion of a ventilation tube can normalize the child's hearing, but experience has shown that the ventilation tubes quite often are extruded rapidly and the symptoms recur. Most parents immediately accept that a child has to be treated with a hearing aid if they are informed about the problem. It can be difficult to have the child accept the hearing aid, but with collaboration between the otolaryngologist and the psychologist in support and instruction, in most cases it is possible to obtain a successful hearing aid treatment.

Conclusions. In general it must be postulated that for the groups of children mentioned treatment with ventilation tubes immediately will restore hearing to the level it was prior to development of SOM. Disadvantages of this treatment depend upon to which hearing loss category the child belongs.

ADVANTAGES AND DISADVANTAGES OF TREATMENT WITH VENTILATION TUBES OVER A LONG OBSERVATION TIME

Jens Ulrik Felding, MD

This problem is most complex. One has to realize that symptomatic treatment of a disease with an often short duration automatically will give few advantages in the long run. These advantages can even be difficult to measure. Furthermore, changes in indications for treatment also can give changes in the complications of the treatment that we are not yet able to measure.

One has to consider that with the final evaluation of advantages and disadvantages of intubation some advantages over a short observation period can outweigh some disadvantages over a long observation time. On the other hand, a documented uncomplicated spontaneous course of disease will shift the focus to the complications.

It should be noted that the child will have been examined after extrusion or removal of the last ventilation tube. Then it is assumed that the secretory otitis media (SOM) period has ended for the child.

Data are available from the relevant literature[1] and from an epidemiologic and prospectively randomized investigation performed at the Department of Otolaryngology at Hjorring Hospital.[2] It included 333 children with SOM at the ages of 3, 6, and 9 years.[2]

Furthermore, a preliminary report from a randomized investigation will be detailed. In this investigation children with bilateral SOM were observed for 4 months before they were randomized for insertion of a ventilation tube in one of the ears. The following factors were evaluated: ear discharge, perforation, chronic otitis media, adhesive otitis, development of cholesteatoma, permanent changes of the eardrum, development of the mastoid air cells, and hearing. In general, the factors mentioned above were represented in all patients, but with low incidence. In many cases the influence of insertion of a ventilation tube cannot be distinguished from the spontaneous course of the disease. Eventual important positive factors such as lack of development of chronic otitis media, adhesive otitis media, or cholesteatoma, as well as mitigation of intellectual development, have not been measured.

The higher incidence (100%) of changes of the eardrum and the tendency toward poorer hearing in the ears treated with a ventilation tube as compared to the untreated ears (approximately 6 dB) has to be weighed with our knowledge about the advantages of a short observation time and the disease's spontaneous course.

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CONSENSUS: WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF INTUBATION, BOTH LONG-TERM AND SHORT-TERM?

Intubation involves the insertion of a plastic or steel tube through the eardrum after fluid in the middle ear has been suctioned out. Short-term anesthesia is required, and an otomicroscope must be used. The operation may be carried out either by ear specialists in general practice or by doctors working in the ear clinics of hospitals.

Intubation is performed in order to ventilate the middle ear. Repeated occurrences of acute infection of the middle ear may also require intubation, but in the following we will confine ourselves to a description of intubation in connection with secretory otitis media (SOM).

The surgical technique was first employed in the beginning of the 1950s. Within the period from 1975 to 1985 the number of treatments quadrupled, so that 25,000 to 30,000 intubations are performed yearly. Over 80% of these treatments are carried out in otologists' offices. Intubation is performed more or less exclusively on children, and primarily children of preschool age.

Approximately 80% of all children will, in the course of childhood, experience a short-term or relatively long-term occurrence of SOM. At present, 20% to 25% of these children will be treated by surgical intervention.

Expert testimony on intubation has stated that up to 40% of the children in Denmark will be candidates for surgical intervention. The data on page 7 may offer a reference point, since it is stated that 10% of children will have SOM for longer periods of time (sometimes several years), while approximately 15% of children will experience several episodes of SOM of 3 to 9 months' duration and 15% will have a single episode of SOM lasting 3 to 9 months.

For the Panel, one point of uncertainty has been the extent to which the very significant percentage of children treated by intubation is in accordance with the criteria for treatment cited by the expert group. In addition, the question as to whether the criteria for treatment are too broadly defined has also been raised.

The short-term advantage of intubation is that the hearing is immediately normalized in patients with SOM, and the feeling of fullness in the ear vanishes. The child's potential for linguistic development is thereby improved. Even though permanent improvement in linguistic development as a result of intubation has not been proven, it is the opinion of the Panel that this form of surgical treatment is of particular importance in relation to handicapped children with SOM — especially children suffering from cleft palate, sensorineural hearing loss, or mental retardation.

With reference to behavioral disorders, neither their occurrence in children with SOM nor the potential effect of intubation upon such children has been documented at the Conference.

The short-term disadvantages and complications of intubation are as follows. Ten percent to 30% of children who have undergone intubation will develop discharge from the ear, and they will often require treatment with antibiotics. Rejection of the tube with subsequent reintubation will occur in approximately 10% to 15% of cases. Blockage of the tube will occur in approximately 10% of cases. Permanent perforation of the eardrum as a result of the tube's being rejected will occur in 0.5% to 2% of cases. The Panel has found it difficult to evaluate the seriousness of the complications cited above.

Total loss of hearing as a complication of intubation cannot be excluded. In one study, the frequency of this complication is placed at 1 in every 12,000 intubations, but there is no reliable documentation available of the limited number of surgical interventions that have been scientifically assessed. As with any other surgical intervention, there is also a certain risk involved in anesthesia.

The only reliable, documented long-term advantage of intubation is thought to be normalized pneumatization (air in the bone surrounding the ear). However, no functional significance can be ascribed to pneumatization.

Theoretic considerations led the expert group to the opinion that the drainage of fluid from and the ventilation of the middle ear result in the normalization of the mucous membrane, with the avoidance of organic changes in the middle ear. However, the expert group could not document this assertion. Thus, in the estimation of certain experts, untreated SOM is the cause of numerous permanent organic changes in the middle ear.

The long-term disadvantages are similarly difficult to evaluate, but at the Conference there was expert consensus that children who have undergone intubation run an increased risk of developing tympanosclerosis (thickening and calcification of the eardrum), since this complication occurs more frequently in children who have experienced intubation than in children who undergo eardrum perforation (paracentesis). This might help to explain a demonstrable difference in hearing of 6 dB between intubated ears and nonintubated ears; but on the basis of the material that is available at the moment, this result is not statistically reliable.

Theoretically, it may be put forward that aeration of the middle ear because of the tube can, later on, lead to the formation of connective tissue and other damage to the mucous membrane.

Generally, it is difficult to estimate whether the present range and scope of intubation treatment lie within reasonable limits. The immediate, obvious short-term advantages must be compared with the long-term consequences — the positive and negative sides of which have as yet not been completely documented, since intubation has only been used as a method of treatment for a relatively short period of time.

To this must be added the continued uncertainty as to the causes of SOM, and also, that intubation is a purely symptomatic treatment. As far as the Panel is concerned, a decisive complex of problems has arisen because a very significant percentage of children born in any one year undergoes intubation even though, according to expert testimony, the indications for such treatment are somewhat ambiguous.

For a widespread form of treatment, rare but serious consequences might become apparent at a later stage and thus affect evaluation of the form of treatment. It has not yet been possible to establish such risks through investigations already undertaken, but they cannot be ruled out. Consequently, the Panel recommends that any increase in the range and scope of intubation as a method of treatment ought to be made with great caution, since first and foremost the rules of safety demand that intubation be carried out only on those children who clearly require surgical intervention. In accordance with this position, therefore, it is suggested that set criteria for intubation as a method of treatment should be drawn up.

PSYCHOLOGICAL AND ECONOMIC CONSEQUENCES OF TREATMENT OF SECRETORY OTITIS MEDIA

PSYCHOLOGICAL CONSEQUENCES OF DIFFERENT TYPES OF TREATMENT

Vibeke Vesterager, PhD

The background for this paper is clinical experience in hearing aid fitting for children with a hearing handicap, most often of a sensorineural type. It is quite seldom that small children have pure conductive hearing losses needing hearing aid treatment, but it is seen now and then in audiologic departments.

The psychological consequences of the following treatments are considered: 1) ventilation tubes for children with and without sensorineural hearing loss, 2) treatment with hearing aids, and 3) "letting time pass" combined with information to parents, teachers, and other persons involved in the daily care of the child.

Treatment 1. Most parents of young children have either directly or indirectly some knowledge about treatment with ventilation tubes. Quite often the parents are ready to accept surgical intervention as the treatment of choice, believing that afterward the child will be cured.

This operation is usually done on an outpatient basis, and if not, the length of hospital stay is short enough that the experience is not traumatic for the child. Children with normal inner ear function will have an immediate although not always permanent hearing improvement, which will be reflected in the child's increased communication possibilities in everyday situations. For those children already fitted with hearing aids, insertion of the ventilation tube will prevent use of the hearing aid on the treated ear for a short period of time.

Treatment 2. Treatment with hearing aids can be relevant for children in whom insertion of a ventilation tube previously has been attempted without permanent effect (ie, in children with cleft palate). Most often there will be immediate hearing improvement without the disadvantages seen in hearing aid treatment of other types of hearing losses.

Treatment with a hearing aid indicates to others that the patient has a handicap; the visibility of the aid can be a benefit for the child who will then avoid misinterpretations such as "He doesn't want to listen" or "He only hears what he wants to hear." From a psychological aspect, the hearing aid's visibility mostly causes problems for the parents. A thorough knowledge of the individual child's reactions and habits is necessary under all circumstances, if hearing aid treatment is going to be successful. Furthermore, close cooperation among parents, teachers, the staff of the audiologic department, and others is required.

Treatment 3. One might choose to "wait and see" on the basis of experience that secretory otitis media quite often will improve spontaneously. It is important that parents are informed about the consequences a conductive hearing loss can have on the daily functioning of the child, so that the behavior of the child is not misinterpreted as inattentiveness, rudeness, etc. Children with fluctuating hearing levels can react by being irritable, fidgety, and noisy at times; the child may even show a tendency toward being withdrawn. These reactions have to be clarified for the parents to avoid any misinterpretations and in order that precautions can be taken.

Summary. From a psychological point of view the optimal treatment is one that considers the individual child's needs and abilities along with a use of the resources available in the close environment that can support the child in a given treatment program. As a group, young children are especially vulnerable to the consequences of an unidentified hearing loss. It is especially in this period of life that the fundamental security and emotional contact with the surrounding environment are established. At the same time of life, the learning of language and concept formation are taking place.

ORGANIZATION OF TREATMENT

Jan Steglich-Petersen, MD

In 1985 the Danish socialized medical system paid otolaryngologists with private clinics for approximately 23,200 operations in which a ventilation tube was placed in the eardrum. It is estimated that approximately 4,000 children were intubated in one ear and 9,600 bilaterally, for a total of 13,600 children treated with ventilation tubes.

The socialized medical system expenses for intubations on children, approximately 23,200 intubations, was approximately 10.2 million kroner ($1.5 million). The total costs of medical treatment by otolaryngologists was 145 million kroner ($21.3 million); hence, the price for ventilation tubes was 7% of the otolaryngologists' total costs.

Besides the mentioned 13,600 children, 2,400 children were intubated during a stay in a public hospital. We do not know the expenses for this.

Altogether, 16,000 Danish children were treated surgically for secretory otitis media with insertion of 27,600 ventilation tubes in 1985.

ECONOMIC CONSEQUENCES OF DIFFERENT TYPES OF TREATMENT

Peter Ellermann-Jensen, PhD

Economic analyses of different types of treatment can be divided into 1) socioeconomic analyses and 2) expense analyses. Socioeconomic analyses evaluate whether the effect of the treatment is reasonable compared to the increasing amount of used resources. Expense analyses involve making a statement justifying the increase in resources necessary for performing a treatment.

As one of the goals of this Conference is to clarify the effect of different types of treatment of secretory otitis media, only expense analyses are presented here (see Table). It must be mentioned that only expenses associated with the treatment and follow-up are considered. Consultation and investigation prior to a treatment are not included, as these consultations will take place regardless of whether treatment is performed or not.

On the basis of background information from general practitioners, otolaryngologists, hospital staffs, and time studies on otolaryngology operating rooms, the costs of different types of treatment have been calculated. In the Table the expenses of the different types of surgical treatment are compared with the number of operations performed, calculated by use of public statistics. The direct expenses for medicine are considered to be approximately 4 million kroner per year, but this is quite uncertain.

The expense analyses give no information as to whether the money could have been used in a better way or not. In considering the substituting of different types of treatment, it must be mentioned that the groups of patients are not completely identical and thereby not suitable for comparison.

If a longer observation period is substituted for treatment, the additional observation costs will on average be 140 kroner ($20) for each follow-up audiogram by an otolaryngologist.

ESTIMATE OF EXPENSES FOR SURGICAL TREATMENT OF SECRETORY OTITIS MEDIA

	No. of Treatments Per Year	*Cost Per Treatment (Kr)*	*Total Cost Per Year (Kr)*
General practitioners			
Paracentesis due to SOM	560	220	123,200
Otolaryngologists			
Intubation due to SOM			
Unilateral	5,310	1,350	7,168,500
Unilateral including adenoids	1,000	390	390,000
Bilateral	10,620	1,820	19,328,400
Bilateral including adenoids	2,620	390	1,021,800
Paracentesis due to SOM			
Unilateral	5,430	420	2,280,600
Unilateral including adenoids	310	390	120,900
Bilateral	2,340	570	1,333,800
Bilateral including adenoids	190	390	74,100
Adenoidectomy due to SOM	690	1,000	690,000
Hospital treatment			
1,157 discharges (in 1985)		2,100	2,429,700
Total costs			34,961,000

1 US dollar = 7 kroner.
SOM — secretory otitis media, Kr — kroner.

CONSENSUS: WHAT ARE THE PSYCHOLOGICAL, ORGANIZATIONAL, AND ECONOMIC CONSEQUENCES OF THE DIFFERENT METHODS OF TREATMENT OF SECRETORY OTITIS MEDIA?

Around 80% to 90% of all children suffer from secretory otitis media (SOM) once or more before school age. Secretory otitis media must therefore be regarded as a normal childhood illness, and it is essential that the national health service be able to deal effectively with the disease.

Today it is mainly otologists in general practice who are responsible for specific observation and treatment. It is known that about 15,000 children undergo intubation in one or both ears in the course of a year, a statistic that gives 25,000 to 30,000 intubations. To what degree otologists in general practice observe the course of the disease is unknown; but judging from the number of children who have been operated upon, one can say that there must be, constantly, a very large number of children either under observation or in treatment in the clinics of Danish otologists.

At the hospitals a number of intubations are carried out on an ambulatory basis, but the present number is unknown. To this must be added some 1,200 hospitalizations per year, during which a long-term tube is often inserted.

It is the Panel's impression that general practitioners do not consistently distinguish among different types of inflammation of the middle ear. Those investigations of illness patterns in general practice that are available cannot be used to illuminate the range and character of observation and treatment of SOM. It is also the Panel's opinion that children, parents, health visitors, teachers, and general practitioners must learn to recognize the disease.

This relative degree of ignorance means, in fact, that the present-day treatment of SOM is dominated by otologists in general practice — a regrettable situation, since SOM is thereby treated out of its context, even though it is a common childhood illness.

Economics. There are at the moment no economic investigations of SOM. It has been calculated, however, that the total yearly expenditure on surgical intervention and treatment amounts to about 35 million kroner ($5 million), 32 million ($4.6 million) of which is claimed by specialists in general practice. This figure includes expenditure on surgical intervention, anesthesia, and subsequent checkups. It should be noted that total expenditure on observation and treatment of SOM is in fact much higher, since patients who have undergone surgical intervention represent only a minor fraction of the full patient group. In 1985 the health insurance authorities paid out 145 million kroner ($20.7 million) in all to approximately 170 otologists in general practice in Denmark. About 15% of this sum covers surgical treatment of SOM and subsequent checkups.

Organizational Proposals. Within the Danish National Health Service it is accepted tradition for observation and treatment to be initiated by the general practitioner. Most incidences of episodic illness can be handled in general practice. Specialists and hospital departments are called upon only when the resources of the general practitioner have been exhausted. It is the Panel's impression that general practitioners are not sufficiently involved in the observation and treatment of SOM.

If, therefore, general practitioners are to take up their traditionally central role, it will be necessary to implement a systematic in-service training program dealing with SOM. It will also be necessary to purchase an impedance audiometer. Thus, the Panel suggests that a trial project should be initiated in two Danish counties, the aim of which is to involve general practitioners and other health service personnel more actively in the observation and treatment of SOM.

A general practitioner who has had extra training and who is technically well equipped can, to a far greater extent, attend to the observation and treatment of children with SOM. Naturally, there will continue to be many children who must be periodically checked and treated by otologists in general practice, but there will also be the opportunity of sending many of these children back for continued checkups to their own general practitioner, who knows the child's social environment. As it is, the general practitioner sees nearly all children in connection with routine examinations. Therefore, an excellent opportunity is already available for investigations into a child's hearing to be undertaken in general rather than in specialized practice, while still satisfying specialized requirements.

This proposal implies that the otologist's time can optimally be spent on those difficult cases that among other things require surgical intervention, while the routine observation can be carried out by the family doctor. In the two counties in which the trial project is to be implemented, a special fee for the general practitioners involved is to be agreed upon, together with obligatory extra training. An impedance audiometer for each general practice will be purchased. A consultants' agreement will be reached under which otologists in general practice will visit participating general practices on a regular basis. A separate system for fees will be agreed upon.

General practitioners will be able to take a more active part in the observation and treatment of SOM during the regular checkups and examinations of their young patients.

Health visitors should be drawn into the trial project through their regular home visits, during which they can discuss with the parents the importance of close contact with a young child suffering from episodic reduction of hearing. Health visitors should give the parents information about SOM and point out that the illness may well cure itself in the course of time — although, like any other illness, it requires special care. Finally, the trial project is to be scientifically evaluated.

PROPHYLAXIS AND FUTURE RESEARCH IN SECRETORY OTITIS MEDIA

CAN SECRETORY OTITIS MEDIA BE PREVENTED?

Bengt Zachau-Christiansen, MD, PhD

Pediatricians all over the world have been engaged in the problems related to secretory otitis media (SOM), but there do not seem to be any reliable results in the literature concerning prevention of this disorder.

Textbooks on pediatrics[1,2] do not inform about results of prevention by intubation, long-term treatment with antibiotics, or chemotherapy (sulfonamides); neither are results mentioned of adenoidectomy or hyposensitization with the allergens presumed to be involved, although they describe trying such treatments. Adenoidectomy and intubation have been described today during the Danish Consensus Conference on Secretory Otitis Media. The papers presented have not supported such treatment, nor antibiotics, as bacteria seldom are found in the fluid.

Although allergic diseases are common in children, Storm et al[3] have not found any correlation to secretory disease in an intensive Danish epidemiologic study. In the 1960s Zachau-Christiansen and Ross[4] made an epidemiologic study of infants: 12% of 8,000 infants in a prospective child health study had otitis media during infancy. At the 1-year examination 11% had bronchitis, which was related to bad housing and to care in day-care institutions, but also to birth weight, as 16% of full-term infants had been asthmatic during infancy, as had 40% of low birth weight infants. No relation was found between allergic diseases and otitis media. Robinson,[2] however, states after his survey of the literature that children with secretory otitis have three times more allergic manifestations than children without secretory otitis.

It is well known[4] that children with day-care attendance have two to three times more upper respiratory tract infections than children cared for at home. In a recent American study Fleming et al[5] found that 6% of children under 3 years had had otitis media during the 2-week period before the parents were interviewed. If living conditions were crowded, this disease appeared in 17%; if the child attended day-care, 39% were found to have otitis media. They did not ask about secretory otitis, and they do not find the same significant influence of parental smoking on otitis as they found on bronchitis.

Uldall[6] from Denmark has published a large interview-study concerning upper respiratory tract infection in 10-month-old, 2-year-old, and 4-year-old children. On the day the parents received his questionnaire such infections were reported in twice as many children cared for in an institution as those cared for at home. If he asked for children with more than two upper respiratory tract infections in the last 3 months that had been so severe that the child had been unable to play, he found a difference factor of 7. Uldall did not specifically ask for information concerning otitis media, as he believed that this diagnosis was difficult for parents to report.

The importance of institutional day-care upon SOM has also been evaluated by Tos et al,[7] who found that 24% of children 2 years of age placed in day-care institutions had secretory otitis, compared to 8% of children in private day-care and 5% in children with home-care. Fiellau-Nikolajsen[8] has reported that secretory otitis disappears more slowly in children from day-care institutions than in other children. Jorgensen-Birch et al[9] found that day-care institutions with mineral fibers for insulation may be especially dangerous. Although Roberts et al[10] have not been able to find any relation between early SOM and retarded verbal and academic performance, as their study population was small (61 children), they state at the end of their paper, that day-care institutions, with their high incidence of secretory otitis, may be disadvantageous for children.

As no significantly advantageous otologic, antibiotic, or allergologic treatment for secretory otitis is reported, the only preventive handling seems to be avoidance of early day-care institution attendance, as it has been significantly proven that such attendance increases the incidence of secretory otitis and upper respiratory tract infections and prolongs the course of SOM.

In modern industrial society, with demands for work outside the home for both parents, avoidance of placing children in day-care is difficult. A further decline in birthrate is not desired. Better legislation for longer parental leaves from work during the first and second years of the child's life, and smaller nurseries for infants, for example from professional day-care with a maximum number of four children, may be preventive of otitis media.

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RESEARCH AND EDUCATION IN THE FUTURE

Mirko Tos, MD

Research on the many problems of secretory otitis media (SOM) in the past 10 to 15 years has been intense, and some important results have been obtained. Still, many questions are unanswered or are partially answered; only a few of the most important ones will be mentioned here.

1. Histopathologic studies have shown that the main cause in the pathogenesis of long-lasting cases of SOM is a change of the middle ear mucosa to a secretory mucosa producing mucus. There still is disagreement about whether long-standing reduced function of the eustachian tube alone without infection can result in a change of the mucosa, or if an infection always has to be present in the middle ear mucosa to make this change. This question also has therapeutic significance, for instance, in the discussion of whether ventilation of the middle ear is mandatory for the course of the disease or if antibiotic treatment is sufficient to obtain a permanent cure.

2. Regarding the function of the eustachian tube, several unanswered questions remain concerning the mechanism of tubal opening, transportation of air through the eustachian tube, the function of the eustachian tube related to edema and hyperplasia of the mucosa of the eustachian tube, and the drainage function of the eustachian tube. No good clinical tests exist to investigate the function of the tube. Furthermore, our knowledge of the changes of gas transportation through the middle ear mucosa and the composition of gases in the middle ear under normal and pathologic conditions is insufficient.

3. Microbiologic and immunologic research has shown that *Pneumococcus* and *Hemophilus influenzae* are the most common bacteria in the middle ear secretion and that the prevalence of *Branhamella catarrhalis* and of β-lactamase–producing *H influenzae* is increasing. The extent to which these bacteria are pathogenic in this disease and how often these bacteria enter the middle ear later on in the disease via new bouts of acute otitis media are not clear. Furthermore, the role of anaerobic bacteria and viruses is unknown. This type of research will have influence on the treatment.

4. The last 10 years of epidemiologic studies have shown that the disease will appear in at least 80% of all Danish preschool children. Fifteen percent will have brief episodes of SOM; 25% recurrent, brief periods of less than 3 months' duration; 15% prolonged periods of 3 to 9 months' duration; 15% prolonged, recurrent cases; and 10% very long-lasting cases of SOM. The cases with brief episodes under no circumstances will have to be treated surgically; but the very prolonged cases under all conditions will have to be treated surgically, because persistent cases will result in a considerable hearing loss over time, during a period that is important for the child's development, and furthermore will result in more severe changes of the eardrum. In between these two marginal groups there is a very large group of children in whom there is no agreement about the indication and the optimal time for surgical intervention. The continued epidemiologic studies must have the goal of identifying those children needing surgical treatment.

It could be expected that early treatment might prevent atrophy of the eardrum. Some retrospective investigations seem to indicate that children having a ventilation tube inserted within the first 2 years of life have fewer changes of the eardrum, but a controlled randomized investigation is needed.

5. There still is some disagreement about the effect of adenoidectomy in the spontaneous course of SOM. Altogether, continuous controlled investigations have to be performed to consider if the surgical treatments such as adenoidectomy or insertion of ventilation tubes in the long run can prevent atrophy and retraction of the tympanic membrane in the severe cases. Furthermore, the therapeutic effect of short or long courses of antibiotic treatment must be documented by controlled investigations.

6. Our investigations have shown that screening it not necessary to identify children with SOM. General screening is very expensive, takes a lot of time, and will lead to overtreatment. Better education of general practitioners and pediatricians about the prevalence of SOM among the risk groups, the etiology of the disease, and its diagnosis will make it possible to identify the severe cases at an early age. Continuous education of otologists about the spontaneous course of the disease and indications for treatment will prevent excessive surgical intervention.

CONSENSUS: CAN SECRETORY OTITIS MEDIA BE PREVENTED, AND WHAT KIND OF RESEARCH IN THIS AREA WOULD BE DESIRABLE?

Responses to the questions asked in this report have shown that the causes of secretory otitis media (SOM) have not yet been narrowed down, but that varied and different conditions seem to play a role. In the Panel's view, medical as well as social conditions are of importance, although their actual significance is at present difficult to describe.

Concerning medical causes, the most important factor is infection of the upper respiratory tract, especially viral infections. It has not yet been established whether immunologic and allergic conditions play a role, although the possibility cannot be excluded. Intensified research in this area is therefore required. The medical causes of SOM do not exist in isolation, but in relation to the ordinary circumstances of life, including physical setting, economic conditions, and psychosocial factors.

As concerns the physical setting, previous studies have shown that SOM and upper respiratory tract infections are more frequent in children attending day-care institutions than in children who are looked after either at home or in day-care with only a few other children. The more children packed into day-care institutions, the more the risk of infection. One must also be aware of the harmful effects of modern building materials on the indoor climate. Such building materials as, for instance, formaldehyde slabs, mineral wool ceilings, and possibly concrete cause serious respiratory problems when taken together with inadequate ventilation. Such negative effects are exacerbated by reductions in the cleaning services in day-care institutions. It may also be presumed that this type of physical surroundings will in itself increase the risk of developing an allergic reaction, with subsequent respiratory problems.

A preventive effort in connection with SOM must be linked with an effort to prevent upper respiratory tract infections in small children attending day-care institutions. When the risk of infection is clearly related to the number of children in the room, a further preventive effort must be made to improve cramped physical space. The conditions under which children live in today's Denmark — a great majority of children have to be looked after in day-care institutions for many hours each day — imply an obligation on the part of society to ensure that neither the physical setting nor the organization of such institutions burdens a child's health.

The home environment is also important, given that inadequate accommodation with the same disadvantageous conditions as mentioned above can play a part in causing SOM. Parents' smoking habits are a factor that increases the risk to health even more.

Primary prevention of SOM, therefore, must take these numerous complex factors into consideration, rather than focusing single-mindedly upon medical treatment. It is unacceptable that a significant number of Danish children must suffer a reduction in hearing for shorter or longer periods of time because of conditions that are predominantly socially determined.

There is a pressing need for research efforts to be directed toward all the preventive areas mentioned above, especially with reference to day-care institutions.

SUMMARY AND PROPOSALS REGARDING TREATMENT INDICATIONS

Secretory otitis media (SOM) is a very widespread childhood disease, the symptoms of which can be treated in a number of ways. One option is surgical intervention — intubation — in which a tube is positioned in the eardrum. At the moment, approximately 25% of children born in a particular year undergo intubation. In the last 10 years the operation has become popular, not least because the child immediately regains his or her hearing.

The Panel has weighed the advantages of intubation against the consideration that the disease often disappears by itself. Permanent side effects from the operation cannot be excluded. We lack long-term experience of intubation. However, there has been no investigation that has demonstrated either long-term advantages or permanent disadvantages connected with it. .

In addition, the Panel's deliberations included the fact that intubation is carried out on a high percentage of Danish children, and consequently even enduring marginal advantages and disadvantages will play a societal role. Given the present state of knowledge, it is the Panel's opinion that a cautious, wait-and-see policy as concerns the surgical treatment of SOM by intubation is necessary. The Panel is uneasy about the continually increasing number of intubations, and remains unconvinced that it is always the right children who undergo intubation.

The Panel firmly believes that in the short term, intubation treatment is of benefit in a number of cases. The Panel proposes the following tentative indicators concerning intubation treatment:

1. Cleft palate and blocked eustachian tubes together with SOM.
2. Sensorineural hearing loss with SOM.
3. Repeated occurrences of middle ear infection.
4. Long-term occurrences of SOM with severe symptoms.

Intubation treatment may also be considered if relatively long-term disturbances in behavior together with retarded language development — both of which can be reasonably related to a reduction in hearing caused by SOM — have been observed in a child by family members or the staff of the day-care institution.

It is with this type of child in particular that an indication for treatment is dependent upon close cooperation with people in the child's immediate environment. It is our opinion, therefore, that the primary health sector must assume a central role when a choice between different methods of treatment has to be made. Such organizational alterations must be scientifically evaluated.

The Panel finds it essential that the risk of infection in day-care institutions should be minimized.

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MANUAL FOR USE OF MONTGOMERY® LARYNGEAL, TRACHEAL, AND ESOPHAGEAL PROSTHESES: UPDATE 1990

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BOSTON, MASSACHUSETTS

This manual is designed to instruct the surgeon, the nurse, and, directly or indirectly, the patient on the updated usage of prostheses involved with reconstructive surgery of the larynx, trachea, and esophagus. The silicone tracheal Safe-T-Tube has been modified in an attempt to prevent its being displaced posteriorly into the trachea. The silicone tracheal cannula can be used in place of a tracheotomy tube unless there is aspiration or positive pressure breathing is required. Its success with sleep apnea has been especially gratifying. The salivary bypass tube and the esophageal tube continue to be of use in treating fistulas, strictures, and reconstruction of the cervical esophagus. The laryngeal keel and stent are described and illustrated for use with reconstructive surgery of the larynx.

KEY WORDS — esophageal prosthesis, laryngeal keel, laryngeal stent, salivary bypass tube, silicone tracheal cannula, speaking valve, tracheal fenestrator, tracheal Safe-T-Tube.

MONTGOMERY SILICONE TRACHEAL T-TUBE (SAFE-T-TUBE*)

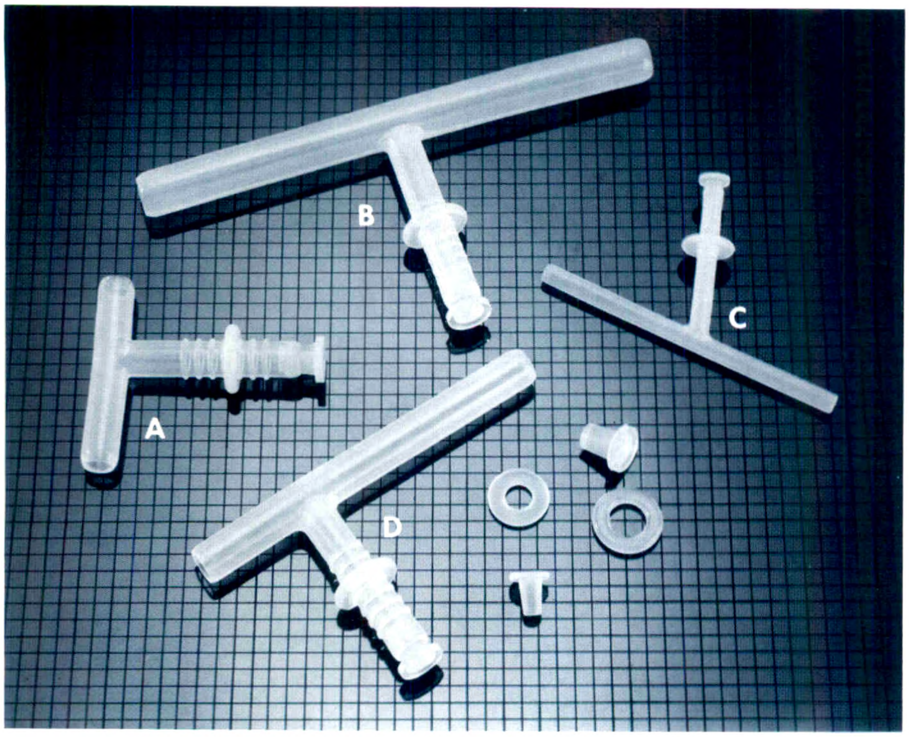

Fig 1. Safe-T-Tube series. A) Standard. B) Extralong. C) Pediatric. D) Thoracic.

DESCRIPTION

The Montgomery Safe-T-Tube is designed to maintain an adequate tracheal airway as well as to provide support in the stenotic trachea that has been reconstituted or reconstructed.[1] Ridges and grooves along the extraluminal limb of the Safe-T-Tube allow a ring washer to be attached in an attempt to prevent posterior displacement of the tube. The Safe-T-Tube is supplied in four styles (Fig 1). The pediatric Safe-T-Tube (Fig 1C) in 6-mm, 7-mm, 8-mm, and 9-mm sizes (outside diameter) has an angled extraluminal limb to facilitate suctioning and airway management. The standard Safe-T-Tube (Fig 1A) is supplied in sizes from 10 mm to 16 mm (1-mm increments; outside diameter). The thoracic Safe-T-Tube (Fig 1D) has an extralong intraluminal limb for thoracic applications. As a life-preserving device, it can be kept in place for many years to stent thoracic tracheal stenosis

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*US Patent #3721233.

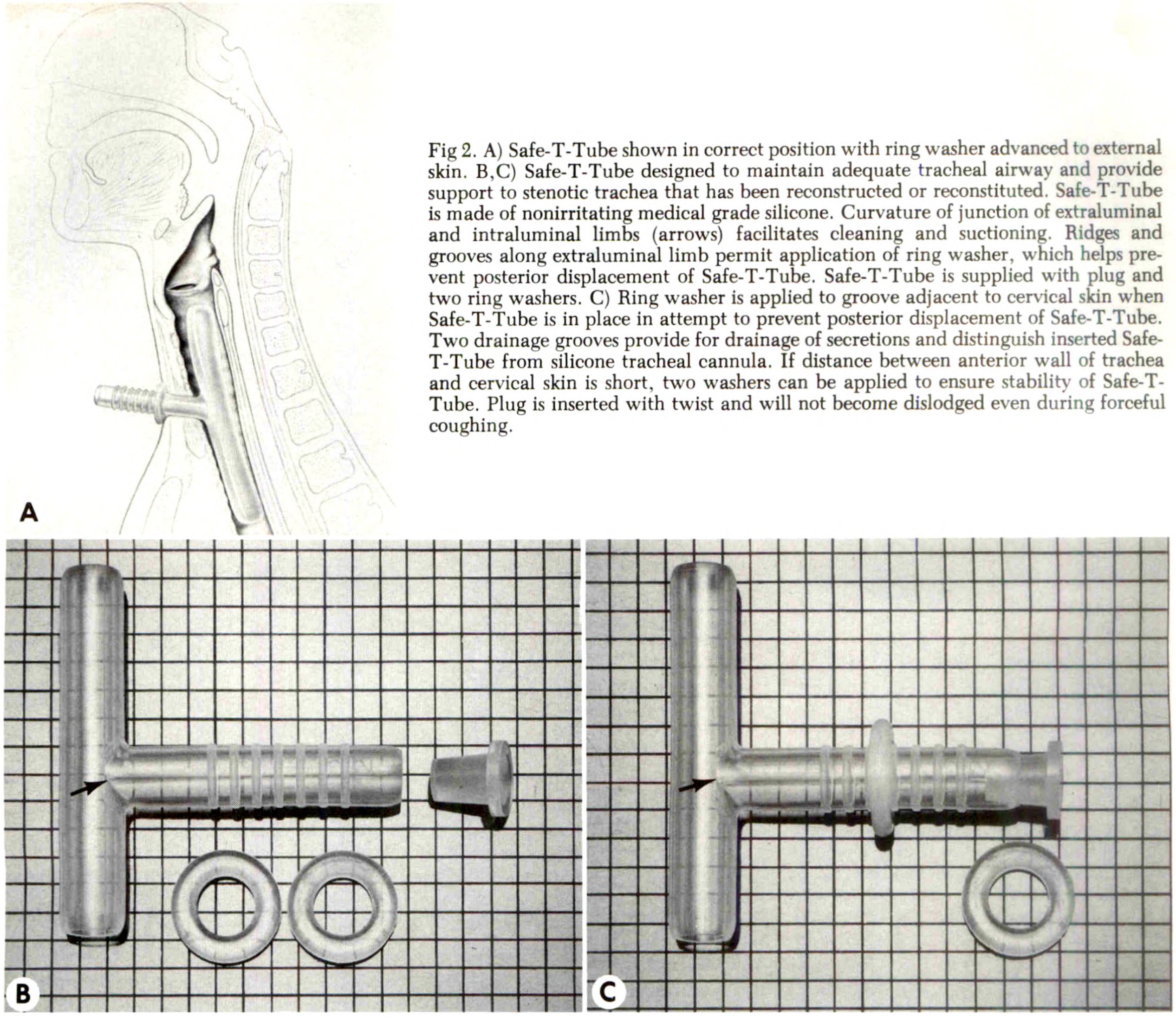

Fig 2. A) Safe-T-Tube shown in correct position with ring washer advanced to external skin. B,C) Safe-T-Tube designed to maintain adequate tracheal airway and provide support to stenotic trachea that has been reconstructed or reconstituted. Safe-T-Tube is made of nonirritating medical grade silicone. Curvature of junction of extraluminal and intraluminal limbs (arrows) facilitates cleaning and suctioning. Ridges and grooves along extraluminal limb permit application of ring washer, which helps prevent posterior displacement of Safe-T-Tube. Safe-T-Tube is supplied with plug and two ring washers. C) Ring washer is applied to groove adjacent to cervical skin when Safe-T-Tube is in place in attempt to prevent posterior displacement of Safe-T-Tube. Two drainage grooves provide for drainage of secretions and distinguish inserted Safe-T-Tube from silicone tracheal cannula. If distance between anterior wall of trachea and cervical skin is short, two washers can be applied to ensure stability of Safe-T-Tube. Plug is inserted with twist and will not become dislodged even during forceful coughing.

that cannot be repaired surgically. The thoracic Safe-T-Tube is available in sizes from 10 mm to 16 mm (1-mm increments; outside diameter). The extralong Safe-T-Tube (Fig 1B) is for distal stenosis and other special cases and is available in sizes from 10 mm to 16 mm (1-mm increments; outside diameter). The intraluminal ends of any Safe-T-Tube may be trimmed; however, it is important to note that the customized ends must be beveled and smoothed prior to insertion to prevent any injury caused by asynchronous motion. The most commonly used sizes for adults are 11 mm, 12 mm, and 13 mm. The curvature at the junction of the external and intratracheal portions of the Safe-T-Tube facilitates cleaning and suctioning (Fig 2). The external portion of the tube can be tilted in an inferior or superior direction to facilitate insertion of suction tubing.

Main features of the Safe-T-Tube are as follows.

1. It serves as both a stent and a tracheotomy tube.
2. Silicone initiates little or no tissue reaction. It does not harden with prolonged contact with body temperature and secretions.
3. The intraluminal portion is of sufficient density and thickness to support a reconstituted or reconstructed stenotic trachea.
4. The intraluminal portion is sufficiently soft so as not to injure the lining or supporting structure of the trachea.
5. The ends of the tube are tapered. Thus, injury does not occur with asynchronous motion between the end of the tube and the tracheal mucosa.
6. Mucus and crusts do not readily adhere to the smooth surface of silicone material.
7. The Safe-T-Tube is widened by the curvature at the junction of its intraluminal and extraluminal portions. This supports the anterior tracheal wall at the tracheotomy site and facilitates suctioning and cleaning.
8. The extraluminal portion is of sufficient length that it can be used with an obese neck. This portion of the Safe-T-Tube can be shortened simply by cutting with scissors.
9. The Safe-T-Tube has been engineered in an at-

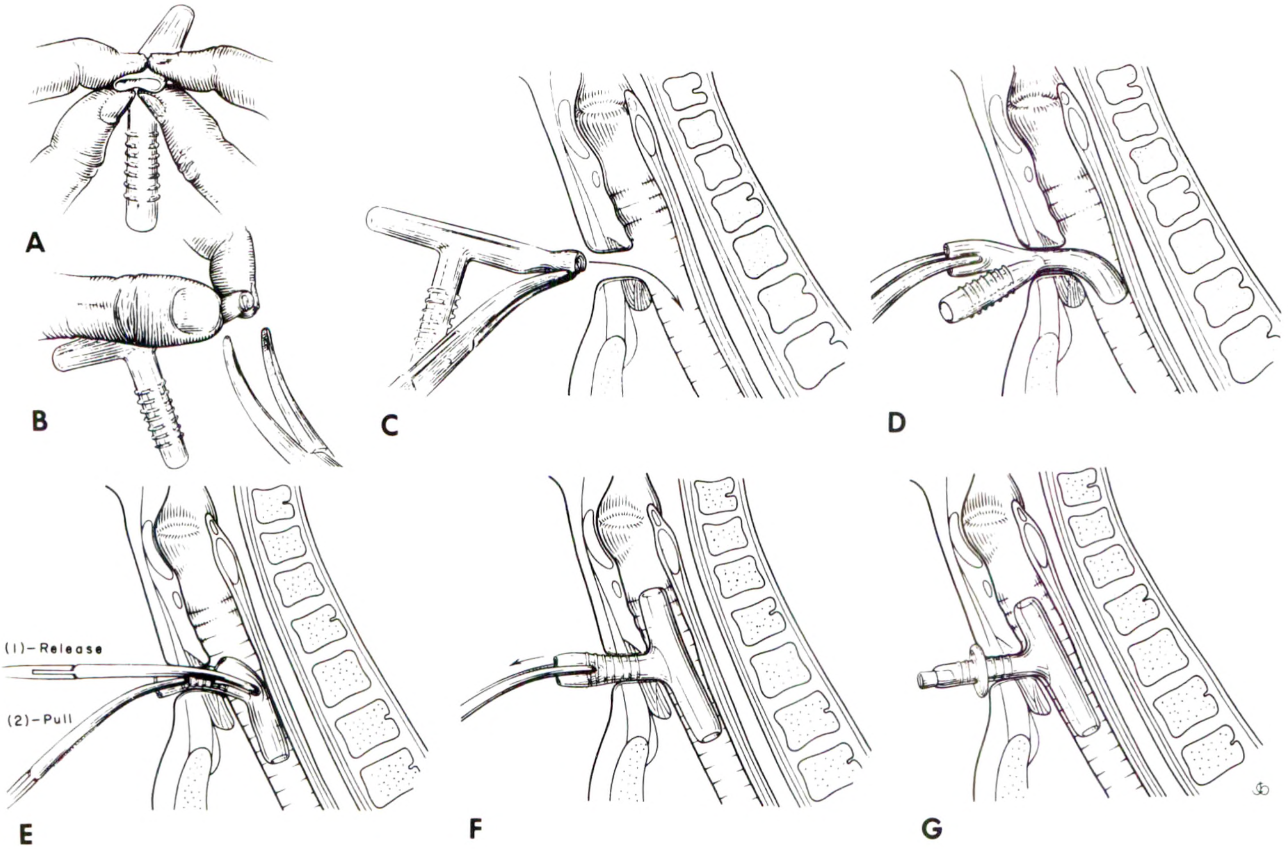

Fig 3. Method for inserting Safe-T-Tube (performed by surgeon). A) End of intraluminal portion of Safe-T-Tube, which is inserted inferiorly, is grasped with index fingers and is folded on itself. B) Crimped end is grasped with hemostat and C) inserted into distal trachea through tracheostome. D) Hemostat is released, and upper intraluminal portion of Safe-T-Tube is grasped with hemostat and directed into trachea. E) Upper intraluminal portion of Safe-T-Tube is directed into trachea until entire intraluminal portion is in place. Hemostat is again released. F) Anterior pull on exterior portion of Safe-T-Tube will direct upper limb of intraluminal portion into place. G) Ring washer is applied to groove adjacent to skin surface, and groove is recorded.

tempt to help prevent accidental displacement of the extraluminal portion into the trachea. Ridges and grooves on the extraluminal portion of the Safe-T-Tube allow for the attachment of a ring washer to help prevent posterior displacement. This ring and groove system permits the Safe-T-Tube to be trimmed to a low profile more acceptable to the patient and allows for the attachment of a speaking valve when indicated.

10. Drainage grooves along the superior and inferior aspects of the extraluminal portion aid in the drainage of secretions and also differentiate the inserted Safe-T-Tube from the Montgomery Silicone Tracheal Cannula, which has only one longitudinal groove (inferior aspect).

11. The Safe-T-Tube is supplied with a plug and two ring washers. The plug is inserted with a slight twist and will remain in place by friction. The ring washer(s) are used on the extraluminal limb to help secure the position of the Safe-T-Tube (Fig 2C).

12. Frequent changing of the Safe-T-Tube is not necessary. In cases in which the trachea could not be reconstructed, it has remained in place and plugged for more than 2 years without a change.

13. Most of the time the Safe-T-Tube remains plugged. This allows for normal respiration and phonation while the Safe-T-Tube is in place.

INDICATIONS FOR USE

The Safe-T-Tube should be used in cases with 1) acute tracheal injuries, 2) a need to support a reconstituted trachea, 3) a need to support a reconstructed trachea, 4) segmental resection and anastomosis, 5) a need to support intrathoracic tracheal stenosis, 6) tracheal stenosis when the cervical or thoracic trachea cannot be repaired, and 7) a cervical trachea that cannot be reconstructed. Currently there are 11 such patients with Safe-T-Tubes in place for periods ranging from 2 to 15 years. A few patients in this group have, over a period of years, regenerated a mucosa-lined trachea supported by scar tissue that has remained adequately patent so that a Safe-T-Tube or a tracheotomy is not necessary. One patient has gone 7 years without a Safe-T-Tube change.

CONTRAINDICATIONS AND PRECAUTIONS

1. The Safe-T-Tube should not be used when there is aspiration or if positive pressure breathing is required. The upper limb must be obstructed with a balloon embolectomy catheter to achieve a closed

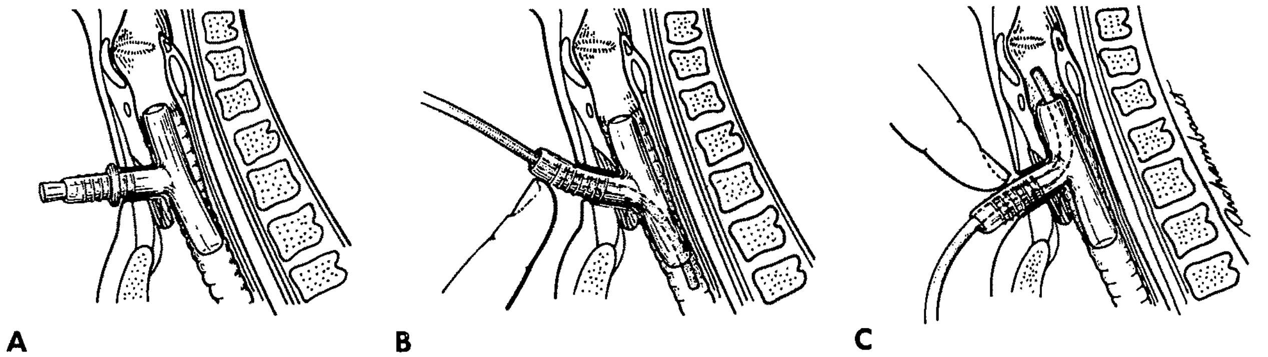

Fig 4. Suctioning of Safe-T-Tube. A) Safe-T-Tube in place with plug inserted into extraluminal limb. Upper intraluminal limb is usually shorter than lower, although tube can be reversed if additional length is needed superiorly. B) When lower segment of Safe-T-Tube and trachea is being suctioned, extraluminal limb is elevated as suction tubing is inserted. C) Suction tubing directed superiorly into upper intraluminal tracheal limb of Safe-T-Tube by bending extraluminal limb in inferior direction.

system for anesthesia.

2. The upper end of the Safe-T-Tube when in place should not rest at the vocal cord level. It should be placed at the level of the laryngeal ventricles or in the inferior subglottis.

3. Because of the decreased inner diameter of pediatric-size Safe-T-Tubes, care must be taken to assure that airway patency remains adequate.

4. Care must be taken to smooth any modified intraluminal limbs of the Safe-T-Tube prior to insertion.

5. A standard tracheotomy tube with obturator in a size smaller than that of the Safe-T-Tube should be kept on hand in the event that emergency removal is necessary.

INSERTION

The Safe-T-Tube should be inserted by a surgeon (Fig 3). Suction apparatus and a large, narrow, curved hemostat are the necessary equipment. Usually the Safe-T-Tube is inserted in the operating room while the patient is under general anesthesia. It can be inserted in the office or at the bedside in patients who have had the Safe-T-Tube in place for several months.

The end of the intraluminal portion of the Safe-T-Tube, which is inserted inferiorly, is grasped with the index fingers and folded on itself (Fig 3A). This crimped end is grasped with the hemostat (Fig 3B) and inserted into the distal trachea by way of the tracheostome (Fig 3C). The hemostat is released. The upper intraluminal portion of the Safe-T-Tube is then grasped with the hemostat and directed into the trachea (Fig 3D) until the entire intraluminal portion is within the trachea (Fig 3E). The hemostat is again released. An anterior pull on the exterior portion of the Safe-T-Tube will direct the upper limb of the intraluminal portion into place (Fig 3F). A ring washer is applied to the groove adjacent to the skin surface (Fig 3G). If the distance between the trachea and the anterior cervical skin is short, two ring washers can be applied to maintain the stability of the Safe-T-Tube.

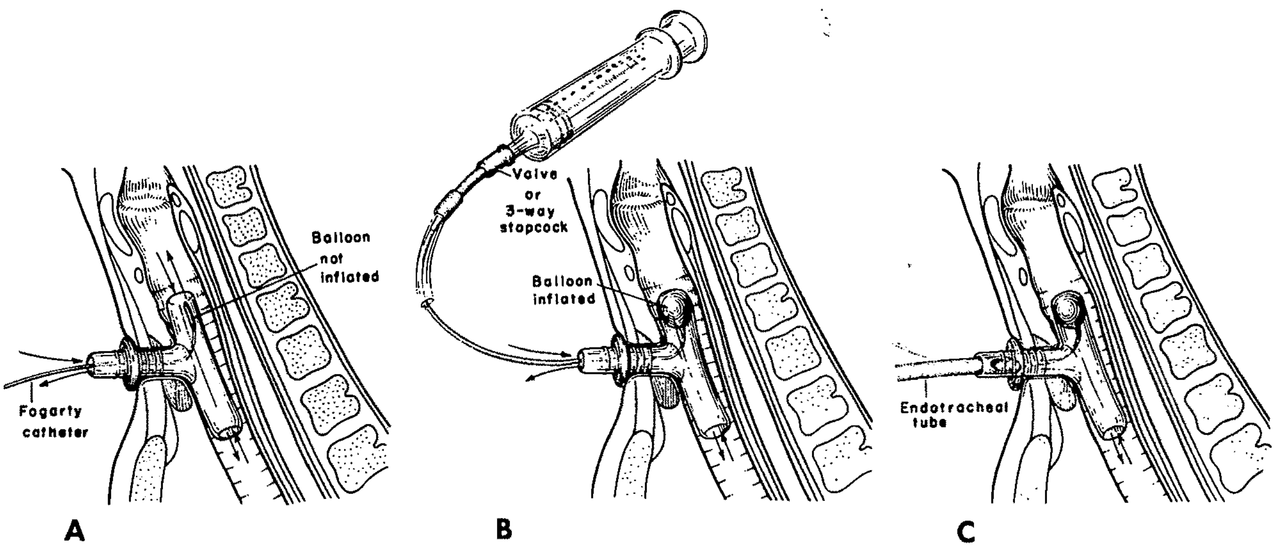

Fig 5. Anesthesia via Safe-T-Tube. Arrows — direction of airflow. A) Balloon embolectomy catheter inserted into upper intraluminal limb of Safe-T-Tube. B) Balloon of embolectomy catheter inflated to obstruct lumen of upper intraluminal limb of Safe-T-Tube. C) Endotracheal tube inserted into extraluminal limb of Safe-T-Tube to establish closed system with distal tracheobronchial system.

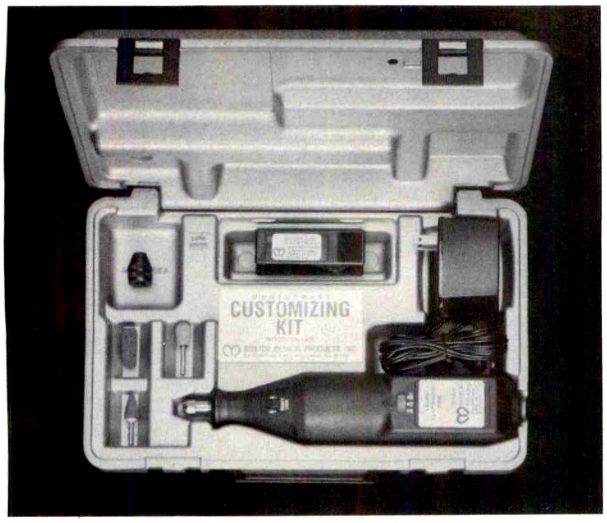

Fig 6. Customizing kit shown with components used to shorten and bevel intraluminal ends of Safe-T-Tube.

ENDOSCOPIC INSERTION

The larynx is exposed with a laryngoscope. The external limb of the Safe-T-Tube is bent against the superior end and grasped with endoscopic forceps. The lower end of the Safe-T-Tube is inserted through the larynx and into the trachea. As soon as the external limb is visualized through the tracheotomy, the forceps is released and the external limb of the Safe-T-Tube is grasped with a hemostat and pulled externally.

SPECIAL FEATURES

Suctioning. The external portion of the Safe-T-Tube can be tilted superiorly and inferiorly to facilitate suctioning (Fig 4). The junction of the intraluminal and extraluminal portions of the Safe-T-Tube is designed for insertion of suction tubing. It is important to select a suction catheter small enough to be easily inserted. As a general rule, most patients require suctioning both superiorly and inferiorly several times a day during the first 10 days after insertion of the Safe-T-Tube. Thereafter, suctioning is required twice daily.

Anesthesia. The loss of anesthetic or air through the upper intraluminal limb of the Safe-T-Tube while it is in place during surgery can be a problem (Fig 5). A simple solution to this problem is to use an arterial embolectomy catheter to obstruct the upper intraluminal limb of the Safe-T-Tube. The endotracheal tube attached to the extraluminal portion of the Safe-T-Tube is disconnected. The embolectomy catheter is inserted into the upper intraluminal segment and inflated. A closed system between the anesthesia apparatus and the distal tra-

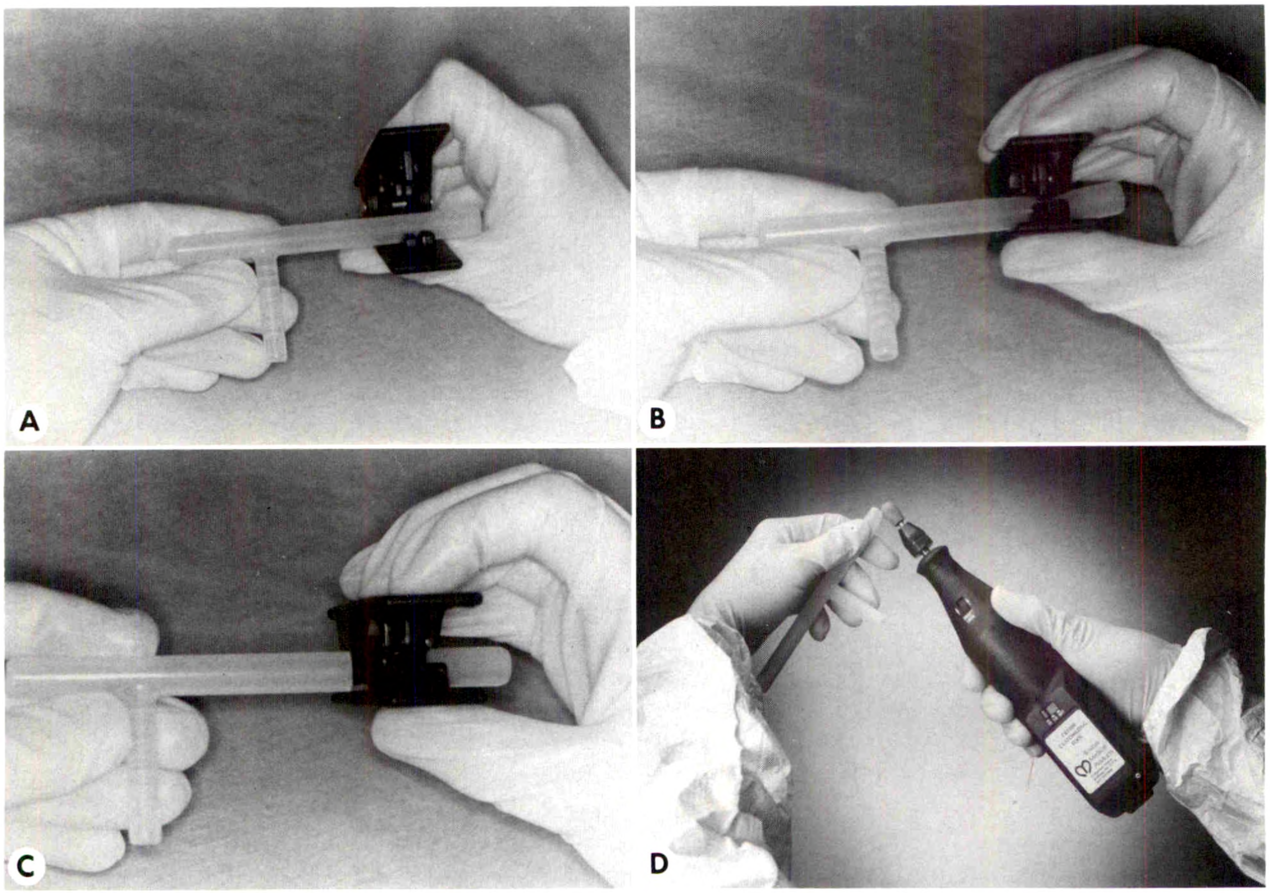

Fig 7. Customizing procedure. A) Safe-T-Tube positioned in cutter. B) Safe-T-Tube being cut. C) Rough cut shown. D) End smoothed with cordless grinding tool.

chea is established when the endotracheal tube is attached to the Safe-T-Tube (Fig 5C). This technique also permits assisted respiration with the Safe-T-Tube in place.

Speaking Valve. If the airway is narrowed above the upper intraluminal end of the Safe-T-Tube by edema or bilateral vocal cord paralysis in the adducted position, a one-way speaking valve (pp 16-17) can be attached to the extraluminal portion of the Safe-T-Tube. The valve is attached to a Safe-T-Tube that has been shortened to the desired length. It is important to make sure that the tube has been trimmed flush with one of the external rings to ensure easy attachment and a proper valve seal.

Customizing. All Safe-T-Tubes can be customized. It is extremely important to bevel and smooth the intraluminal ends of the Safe-T-Tube after shortening. Manual methods for smoothing rough ends include the use of sterile sandpaper and hand filing. A customizing kit is available, specifically designed to shorten and smooth the limbs of the Safe-T-Tube. The customizing kit is shown in Fig 6 and includes a cordless grinding tool with keyless chuck, a tube cutter, grinding stones, a pen and ruler set for measuring and marking the tubes, and a carrying case. The procedure for customizing is as follows.

1. Measure one or both intraluminal ends of the tube to be customized and mark with an appropriate marking instrument (enclosed in kit).
2. The tube cutter has a spring action and is pressed to open. While holding the cutter open in one hand, position the marked end of the tube to be cut over the center of the cutter. Make sure the tube is positioned in the "V" groove of the cutter (Fig 7A).
3. Gently squeeze the cutter closed while keeping the tube aligned in a straight position (Fig 7B).
4. While holding the cutter closed, pull the tube away from the cutter (Fig 7C).
5. Select one of the grinding stones and insert into the grinding tool using the keyless chuck.
6. The grinding tool has two speeds. We recommend using the higher speed to smooth the ends of the tube. Apply the grinding tool to the rough cut end(s) of the tube and slowly work around the edge to bevel and smooth the end. Continue to smooth the end to create the desired beveled edge(s) (Fig 7D).
7. Cleanse the tube of any particulate matter and sterilize before using.

REMOVAL OF SAFE-T-TUBE FROM TRACHEOTOMY

Most patients have not required a change of the Safe-T-Tube before its final removal. On occasion, however, it is necessary to remove and replace the Safe-T-Tube 1) if the intraluminal portion of the Safe-T-Tube becomes partially obstructed and cannot be cleaned, 2) if the Safe-T-Tube is not in proper position, or 3) in an emergency (by doctor, nurse, or relative) if the Safe-T-Tube becomes obstructed (Fig 8). A tracheotomy tube (of smaller size than the Safe-T-Tube) with obturator should be kept on hand to be inserted immediately after emergency removal of the Safe-T-Tube.

To remove the Safe-T-Tube, the external limb is grasped with the thumb and index finger of one hand while the index and second finger of the other hand are pressed against the skin above and below the external limb of the Safe-T-Tube (Fig 8C). The Safe-T-Tube is removed by a steady firm anterior pull (Fig 8D). On rare occasions (if the Safe-T-Tube has been in place for many months), it may be necessary to make a small vertical incision in the skin with cutting current cautery above or below the external limb of the Safe-T-Tube to facilitate removal.

ENDOSCOPIC REMOVAL OF SAFE-T-TUBE

A laryngoscope is inserted to expose the larynx and upper intraluminal end of the Safe-T-Tube. The superior intraluminal end of the Safe-T-Tube is grasped with laryngeal forceps. An assistant grasps the external limb of the Safe-T-Tube with a hemostat and pushes it into the tracheotomy as the operator removes the Safe-T-Tube along with or through the laryngoscope.

PREOPERATIVE AND POSTOPERATIVE ORDERS

Preoperative Workup.

1. Maxi scan (adult) or complete blood count (child).
2. Urinalysis.
3. Chest x-ray study.
4. Soft tissue x-ray studies of larynx and trachea with copper filtration.
5. Electrocardiography (patients over 40 years of age).
6. Regular diet.
7. Preoperative antibiotics: intravenous (IV) antibiotic started as soon as preanesthetic IV is inserted.

Postoperative Orders.

1. Administer antibiotics: ________ continue IV ________ hours postoperatively ________ qid.
2. Maintain constant humidity.
3. When the patient is recovered from anesthesia
   a. Keep the external limb of the Safe-T-Tube plugged if possible.
   b. Use humidified air over the Safe-T-Tube if the limb is not plugged.

POSTOPERATIVE NURSING CARE

The following recommendations were presented by L. B. Shattuck, RN, and S. Weatherford-Moler, RN, at the Twelfth Annual Congress and Nursing

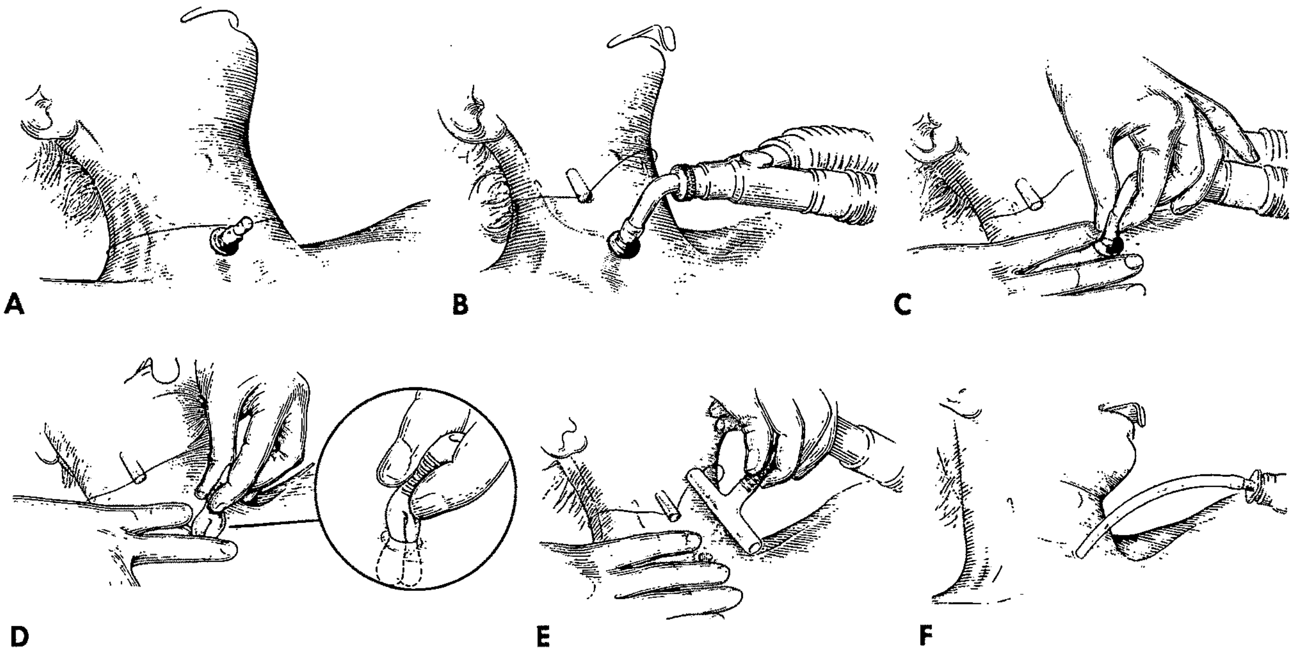

Fig 8. Removal of Safe-T-Tube. A) Patient with Safe-T-Tube in place. B) Plug has been removed. Anesthetic is administered via external limb of Safe-T-Tube. C) One finger is placed above and one below external limb to exert pressure in posterior direction. D) As Safe-T-Tube is pulled from trachea, upper and lower intraluminal limbs buckle toward each other (inset). E) Safe-T-Tube springs back to proper shape after intraluminal limbs part from tracheotomy fistula. F) Endotracheal tube is used until patient has recovered from general anesthesia.

Symposium of the Society of Otorhinolaryngology and Head–Neck Nurses, Inc, Washington, DC, Sept 25-29, 1988.

1. Lavage the tube with 5 to 10 mL normal saline every 2 hours while the patient is awake and every 4 hours during sleep.
2. To loosen thick mucus in the tube, the use of sodium bicarbonate solution (5%, 2 mL) every 4 to 8 hours may be necessary (as ordered by physician).
3. Suction the normal saline from the Safe-T-Tube, using a 12F to 14F suction catheter. It may be necessary to manipulate the external portion of the tube for easier passage of the catheter (refer to Suctioning, Fig 4).
4. Antibiotics are often prescribed.
5. If the Safe-T-Tube is not plugged, humidified air via a tracheotomy collar is necessary.
6. Clean the area around the Safe-T-Tube with hydrogen peroxide every 8 hours as needed.
7. Clean the inside of the tube with a small tracheotomy tube brush saturated with normal saline two times daily. The brush can be obtained from a tracheotomy care kit or from the manufacturer of the Safe-T-Tube. For smaller-diameter Safe-T-Tubes, a standard pipe cleaner can be used in place of the tracheotomy tube brush.
8. For emergencies, have the following equipment taped to the head of the bed:
    a. A tracheotomy tube, the size ordered by the physician.
    b. An adapter for a manual resuscitation bag.
    c. A hemostat to remove any pieces of tube during emergency removal.
9. If the patient shows signs of a partial airway obstruction, ie, stridor, decreased air movement from the tube, or decreased breath sounds,
    a. Place the palm of your hand over the Safe-T-Tube to assess air movement.
    b. Listen for equal breath sounds.
    c. Lavage the Safe-T-Tube with normal saline, suction, and clean the inside with the tracheotomy tube brush.
10. If these measures are not effective,
    a. Stay with the patient.
    b. Have another nurse call the doctor.
    c. Repeat lavaging, suctioning, and cleaning, and if these measures are still not effective, attach a manual resuscitation bag to the Safe-T-Tube and attempt to ventilate.
11. The chances of a complete airway obstruction are slight, ie, no chest movement, no air movement through the tube, or absent breath sounds. However, if this happens and the above measures are not effective, the procedure for removing the Safe-T-Tube is as follows (Fig 8).
    a. Grasp the external limb of the Safe-T-Tube with one hand while holding the skin above and below the insertion site with two fingers of the other hand.
    b. Use a steady, slow pull to remove the tube. Be prepared to grasp the remaining tube with a hemostat if the external limbs tear loose.
    c. Insert the tracheotomy tube.
    d. Suction the airway if bleeding occurs.

SUCTIONING THE SAFE-T-TUBE

Suction the Safe-T-Tube as shown in Fig 4. Key

TABLE 1. CORRESPONDING SAFE-T-TUBE AND TRACHEOTOMY TUBE SIZES

Safe-T-Tube (mm)	*Tracheotomy Tube No.*
6	00
7	00
8	0
9	0
10	2
11	3
12	4
13	4
14	6
15	6
16	8

points about suctioning are as follows (L. B. Shattuck and S. Weatherford-Moler, 1988).

1. Suction both limbs. To suction the upper part of the Safe-T-Tube, apply a gentle downward movement of the external limb. To suction the lower part of the Safe-T-Tube, apply a gentle upward movement of the external limb.
2. Suction only the length of the internal limbs of the Safe-T-Tube. Passing the catheter beyond the intraluminal ends causes coughing and irritation.

HOME CARE EQUIPMENT

(Shattuck and Weatherford-Moler, 1988)

1. Normal saline (salt water).
2. Small tracheotomy tube brush (or pipe cleaner for smaller-diameter tubes).
3. Suction machine.
4. Suction catheters.
5. French collar (optional).
6. Nonsterile 4 x 4 gauze.
7. Cool or heated mist when ordered.

HOME CARE INSTRUCTIONS

(Shattuck and Weatherford-Moler, 1988)

1. With an eye dropper, place 1 to 2 teaspoons of normal saline (salt water) into the Safe-T-Tube every 4 hours, and suction as needed. Some patients may not produce much mucus, so this step may not be necessary.
2. Clean the inside of the external limb of the Safe-T-Tube with a wet tracheotomy tube brush twice a day.
3. Clean the skin around the Safe-T-Tube with hydrogen peroxide solution 3 times a day. Remove any crusts. The use of Betadine solution or Aureomycin (chlortetracycline HCl 3%) ointment may be ordered by the physician.
4. If there is any trouble breathing, check for air movement through the tube with the palm of the hand. The signs of troubled breathing are noise from the tube, difficulty speaking, shallow and fast breathing, anxiety, crowing sounds from the throat, change in skin color to pale or blue, and skin that feels cold and damp to the touch.
5. If trouble breathing is experienced, clean and suction the tube.
6. If there is still trouble breathing, contact the doctor for further instructions.
7. If the tube becomes completely obstructed, pull it out immediately and insert a tracheotomy tube (Table 1). A tracheotomy tube should be with the patient at all times in case of emergency removal. Call the doctor.

MONTGOMERY SILICONE TRACHEAL CANNULA SYSTEM*

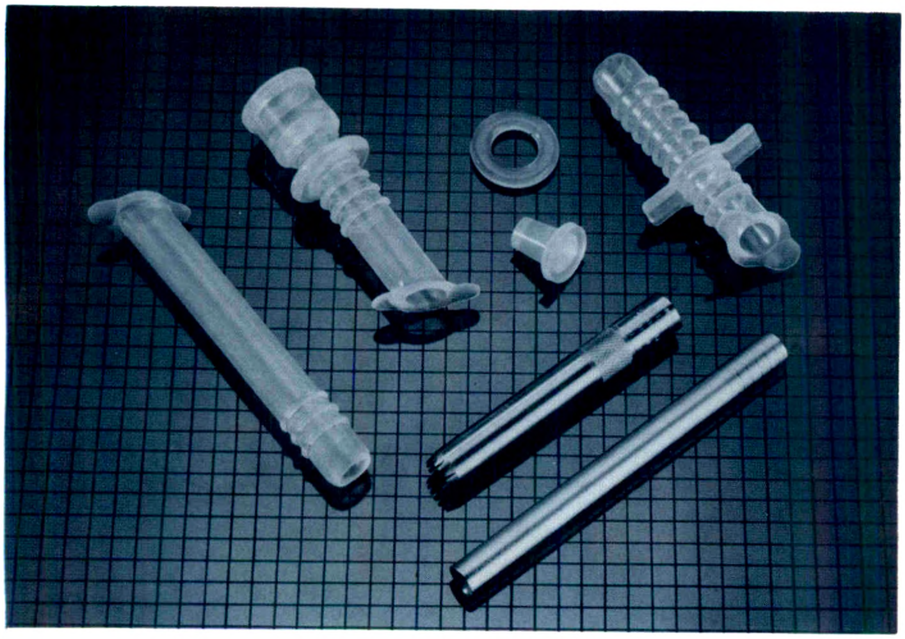

Fig 9. Tracheal cannula system.

DESCRIPTION

The Montgomery Silicone Tracheal Cannula System has been designed to be used in place of a tracheotomy tube and has been used successfully for over 12 years (Fig 9).[2] The main advantage of the cannula is that there is no foreign body projecting into the trachea since the tracheal cannula extends only to the inner surface of the anterior tracheal wall. The silicone tracheal cannula is constructed from medical grade silicone material to which there is little or no tissue reaction. It is flexible and nonirritating. The cannula is available in three diameters equivalent to standard tracheotomy sizes: size 6 (8 mm inside diameter, 11 mm outside), size 8 (9 mm inside, 12 mm outside), and size 10 (10 mm inside, 13 mm outside).

DESIGN FEATURES

The component parts of the Montgomery Silicone Tracheal Cannula include an inner flange that is thin and shaped so as to fit against the contour of the inner anterior tracheal wall. This inner flange is designed so that the vertical dimension is greater than the horizontal dimension. This design allows for ease of insertion into the opening of the anterior tracheal wall and also helps prevent rotation of the cannula once it is in place. The inner flange is fashioned at a 27° angle to the long axis of the tracheal cannula so that the cannula will project straight forward or in a slightly superior direction when inserted (Fig 10). All tracheal cannulas utilize a system of rings and grooves on the extraluminal portion of the tube. This system allows the placement and adjustment of either a faceplate or a ring washer to secure the cannula. There is a groove along the inferior surface of the shaft of the cannula that allows for the drainage of serum and products of inflammation, which may occur during the immediate postoperative period. The groove also identifies the inferior aspect of the tube, serving as a point of reference to indicate if the inner flange has been accidentally rotated out of its proper position. When in place, the Montgomery Silicone Tracheal Cannula closely resembles an adult-size Montgomery Safe-T-Tube. The cannula can be distinguished by its one drainage groove in the inferior position as compared to the two grooves on the extraluminal limb of the Safe-T-Tube.

The silicone tracheal cannula can be trimmed after insertion to allow the application of a speaking valve and to achieve a desired low profile. A No. 11 surgical blade or straight scissors are best suited for trimming the cannula. All cannulas can be custom fitted to various stoma lengths by removing one or more rings and thereby increasing the smooth portion between the intraluminal flange and the first ring (Fig 11). The manufacturer can provide these services.

INDICATIONS FOR USE

The silicone tracheal cannula should be used in cases of 1) sleep apnea (the cannula remains plugged

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*US Patent #4269184.

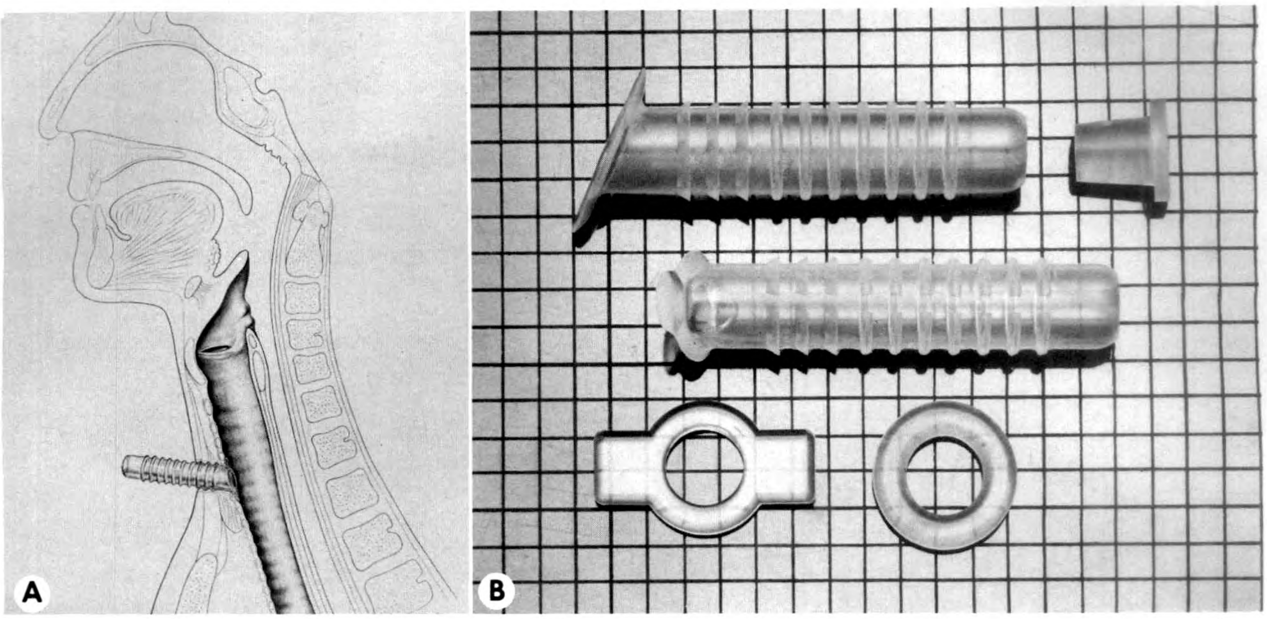


Fig 10. Short-term tracheal cannula designed to be used in place of tracheotomy tube. A) Cannula extends only to inner surface of anterior tracheal wall, eliminating foreign body projecting into trachea. B) Cannula, wing-shaped faceplate, plug, and ring washer. Groove along cannula's long axis assists in drainage of secretions and serves to identify inferior aspect of cannula. First three rings adjacent to flange are triangular to assist in fixing cannula in place and make it difficult to displace anteriorly. Remaining grooves serve to secure faceplate or ring washer in place. Plug has head to prevent introduction too far into lumen of cannula.

while the patient is awake, and the plug is removed when the patient is sleeping), 2) bilateral vocal cord paralysis (temporarily used for trauma or thyroid surgery; permanently used when a corrective operation such as arytenoidectomy is not indicated or has not been successful), 3) laryngeal carcinoma with glottic insufficiency during radiotherapy, 4) removal of the Safe-T-Tube, until it is certain that the airway is adequate, 5) chronic lung disease during suctioning, or 6) intermittent laryngeal insufficiency (neurologic disorders such as myasthenia gravis, head trauma, amyotrophic lateral sclerosis, etc; laryngeal arthritis; chronic laryngitis; and intermittent edema from allergy, inflammation, or radiotherapy).

CONTRAINDICATIONS

The Montgomery tracheal cannula cannot be used for positive pressure–assisted respiration or when the patient is aspirating. In these instances, a cuffed tracheotomy tube is indicated.

INCISION AND INSERTION

A vertical skin incision is used to insert the silicone tracheal cannula (Fig 12A). The medial raphe between the sternohyoid and sternothyroid muscles is identified and incised. The thyroid isthmus is divided and suture ligated (Fig 12B). The anterior wall of the trachea is exposed so that the fenestration can be made at the proper level (Fig 12C).

The fenestration of the anterior tracheal wall is made with the tracheal trephine fenestrator (Fig 13). The tracheal fenestrator consists of an outer trephine knife that fits over an inner sleeve. The trephine knife makes an incision that is 2 mm less than the outside diameter of the corresponding silicone tracheal cannula; the trachea stretches so that it will easily allow the insertion of the diameter of the tracheal cannula. It is important to match the correct fenestrator with the size of the tracheal cannula used to ensure a proper fit. The original tracheal cannulas correspond to a size 6 (8 mm) fenestrator. The size 8 and 10 tracheal cannulas now available correspond to size 8 (10 mm) and 10 (11 mm) fenestrators, respectively. The cutting edge of the trephine knife is designed so that it can both cut and saw. The cutting effect is for the soft tissues of the anterior tracheal wall, and the serrated edge can

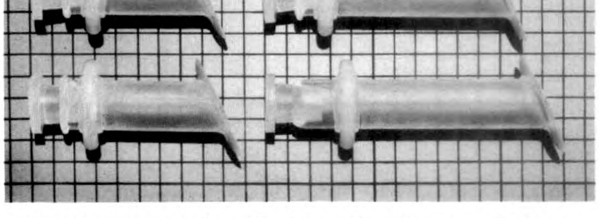


Fig 11. Customized tracheal cannulas. By removal of one or more rings, smooth portion between inner flange and ring washer can be increased to fit different stoma sizes.

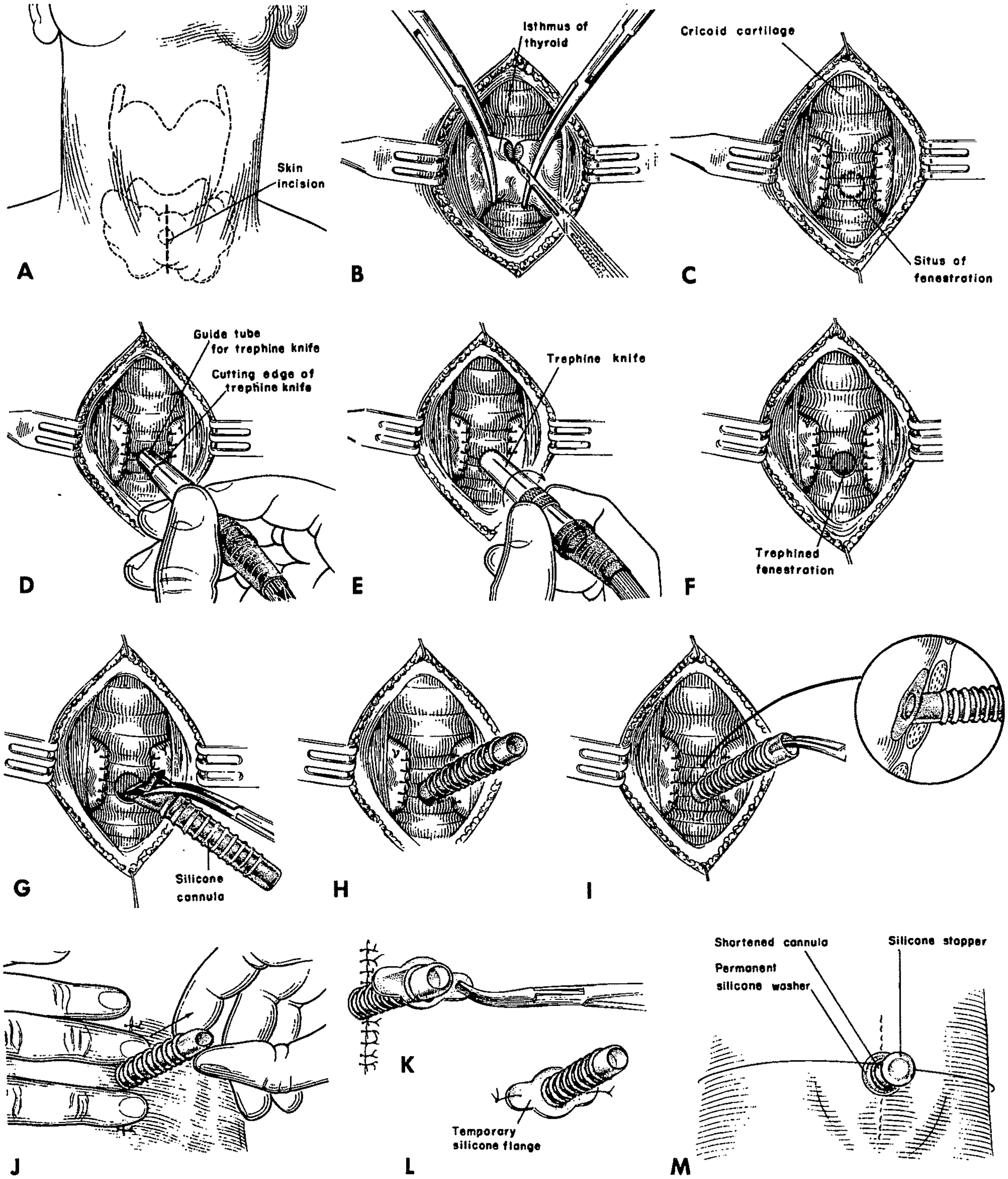


Fig 12. Insertion of tracheal cannula. A) Vertical skin incision made to expose thyroid isthmus. B) Thyroid isthmus is divided and suture ligated. C) Divided segments of thyroid isthmus dissected away from anterior wall. Site for fenestration is indicated. D) Tracheal fenestrator placed over inner sleeve, which is connected to suction tubing and placed against anterior tracheal wall. E) Outer or trephine portion of tracheal fenestrator advanced to tracheal wall after inner sleeve has become adherent to anterior tracheal wall by suction. Core of tracheal wall is cut by rotating fenestrator clockwise. F) Fenestrated anterior tracheal wall. G) Flanged end of tracheal cannula grasped with curved hemostat and inserted through fenestrated tracheal wall. H) Flange is now intraluminal. I) Flange should fit snugly against anterior tracheal intraluminal wall (inset). J) End of cannula pulled anteriorly. K) Following repair of incision, faceplate is advanced to groove adjacent to skin surface. L) Faceplate secured to skin with one 3-0 monofilament suture through each wing. Endotracheal tube can be inserted into silicone tracheal cannula as patient recovers from anesthesia. M) Faceplate has been removed and replaced by ring washer. Silk suture is placed through plug so that it will not be lost when not in use. Plug holder is also available.

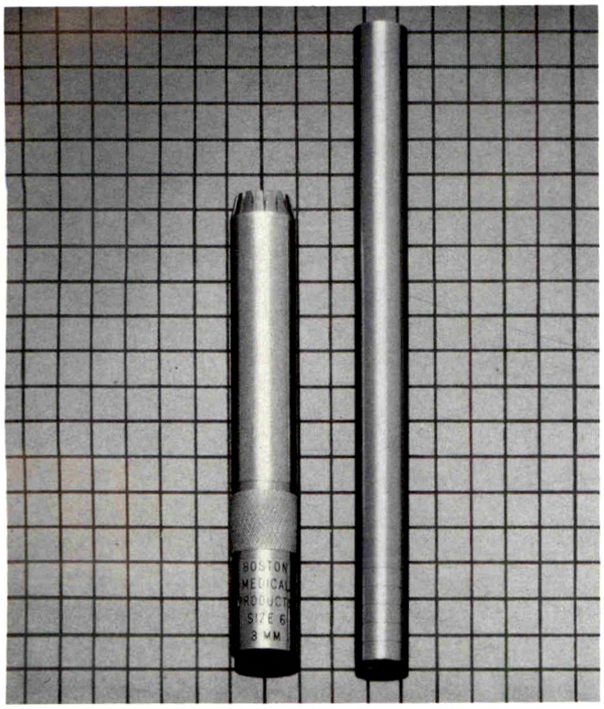


Fig 13. Tracheal fenestrator consisting of outer trephine knife fitting over inner sleeve.

saw through cartilage that has become ossified.

The second portion of the tracheal trephine fenestrator is an inner sleeve that fits inside the trephine fenestrator. The grooved end of the inner sleeve fits into standard suction tubing.

To use the tracheal trephine fenestrator, the inner sleeve is first attached to suction tubing (Fig 12D). The fenestrator is placed over the inner sleeve so that the inner sleeve projects beyond the cutting edge of the fenestrator. The projecting edge of the inner sleeve is then placed against the anterior tracheal wall, to which it immediately adheres because of suction. The outer or trephine portion of the tracheal fenestrator is advanced to the anterior tracheal wall and rotated to incise a core of anterior tracheal wall (Fig 12E). The core of removed trachea either remains adherent to the end of the inner sleeve or passes up the suction tubing. The advantages of this instrument over the previous methods for making a tracheotomy fenestration are that it is simpler, is less traumatic to the trachea, and can produce a perfectly round fenestration in the anterior tracheal wall (Fig 12F). A set of four fenestrators, sizes 4, 6, 8, and 10, is available, housed in a custom reusable sterilization tray (Fig 14).

To insert the silicone tracheal cannula into the trachea, its end is compressed with a curved hemostat (Fig 12G). Thus the end forms a point that can easily be inserted into the lumen of the trachea (Fig 12H). The tracheal cannula is then pulled anteriorly until the inner flange fits snugly against the intraluminal anterior tracheal wall (Fig 12I,J). The cannula is rotated so that the longitudinal groove is at the 6-o'clock position. The wound is closed above and below the silicone tracheal cannula.

The faceplate is applied over the short-term tracheal cannula and is then advanced until it fits fairly close to but not too tightly against the skin (Fig 12K). One 3-0 monofilament suture is placed in each wing of the faceplate to secure it to the skin (Fig 12L). The external end of the cannula can be shortened by cutting with straight scissors. Anesthetic or oxygen can be administered by the tracheal cannula as the patient recovers from general anesthesia. If there is a significant loss of air superiorly into the upper respiratory system, then a Fogarty catheter is inserted and inflated superior to the level of the silicone tracheal cannula (as a temporary measure).

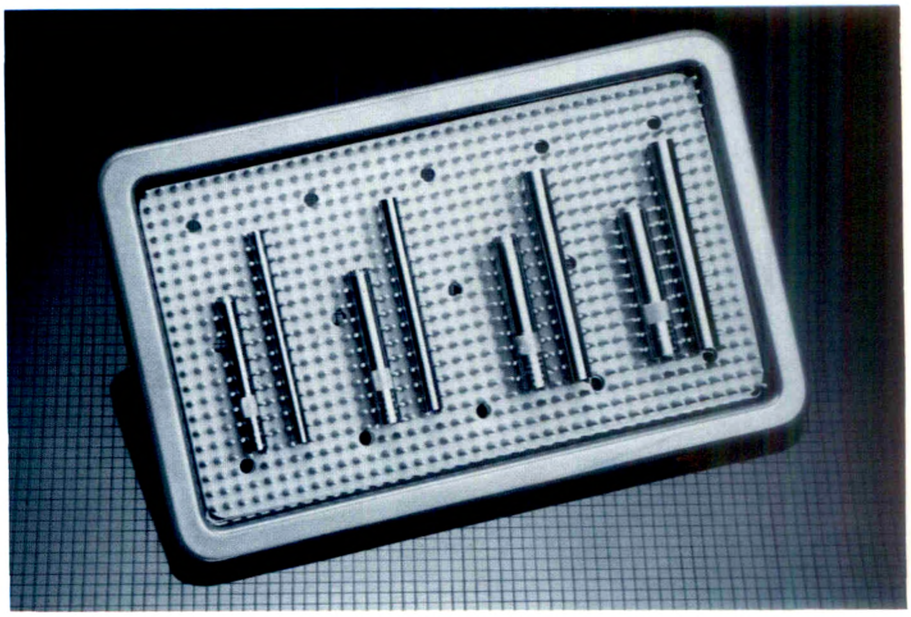


Fig 14. Tracheal fenestrator set showing four sizes of tracheal trephine fenestrators and sterilization tray.

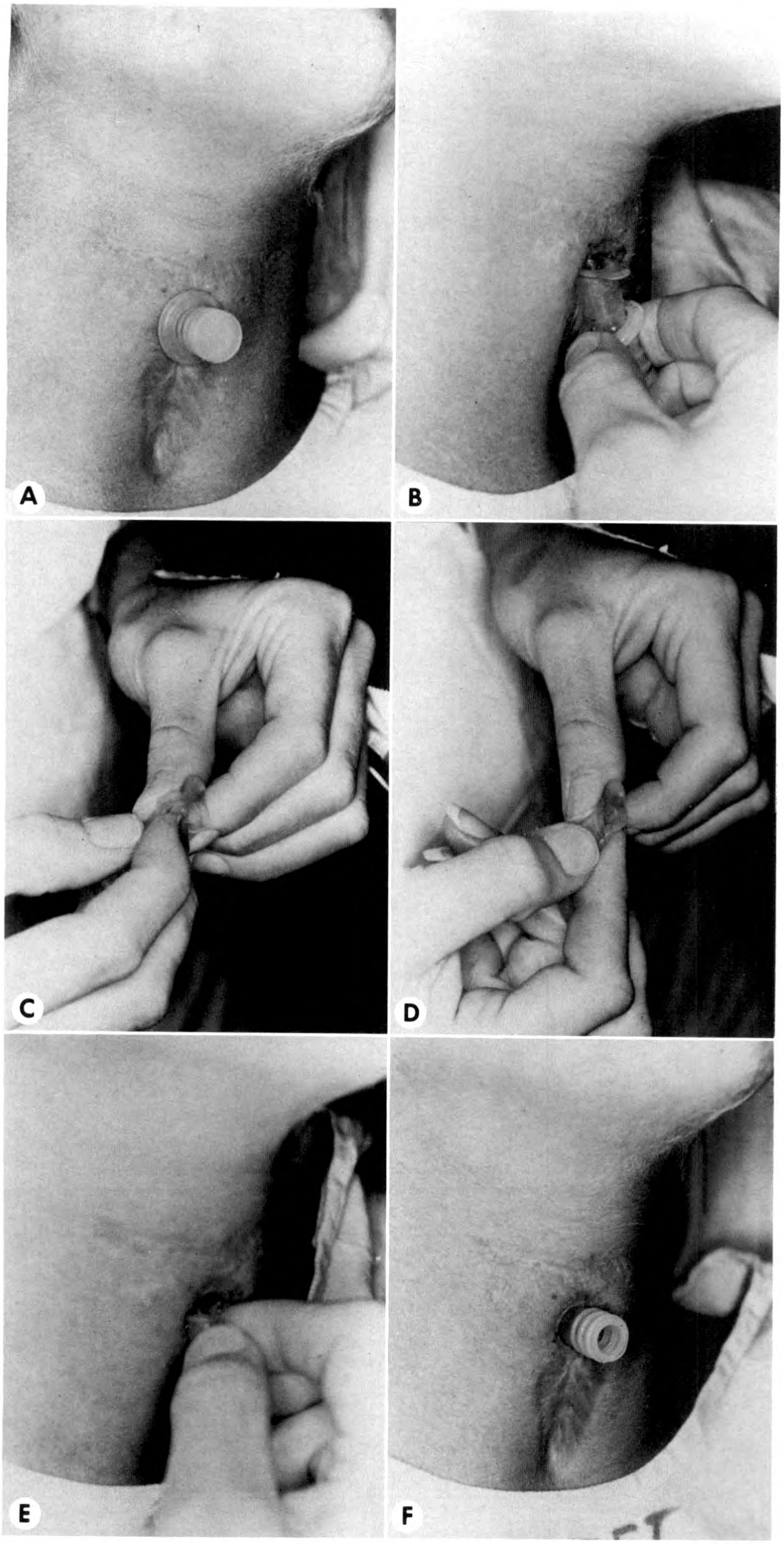


Fig 15. Removal and replacement of cannula by patient. A) This patient is using plugged silicone tracheal cannula after repair of glottic and subglottic stenosis and removal of Safe-T-Tube. During this period of cannula use, she learned to remove, clean, and reinsert it. B) Cannula is removed simply by pulling it forward. C) Lower, or inferior, inner flange is pressed into lumen with index finger. D) Inner end of cannula is squeezed together, greatly reducing its size. This narrow pointed end of cannula is easily slipped into tracheotomy tract. E) End of cannula being pushed into lumen. F) Cannula has been pulled gently forward, engaging it into proper position. It awaits application of ring washer and insertion of plug.

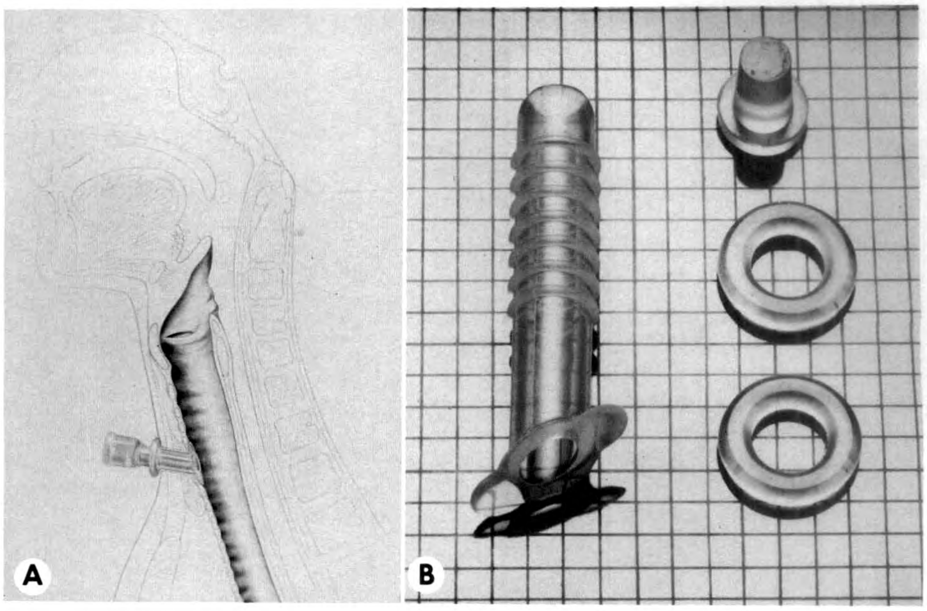


Fig 16. A) Long-term cannula shown in proper position with ring washer and speaking valve applied. B) Long-term tracheal cannula shown with two washers and plug. Surface adjacent to intraluminal junction is smooth to permit and encourage growth of epithelium from both trachea and skin.

INSERTION OF CANNULA INTO EXISTING TRACHEOTOMY

This insertion can be attempted as an office procedure, but most often is best done with general anesthesia. Usually the tracheotomy tract is directed posteroinferiorly. This tract can be straightened by a single vertical midline incision in the skin inferiorly and the trachea superiorly. The tracheal cannulas are sized to correspond to standard tracheotomy tube sizes (6, 8, and 10) for easy reference.

For proper fit of the tracheal cannula for long-term use, the patient's stoma length should be measured and recorded. A stoma measuring kit is available from the manufacturer. The measuring device is simply inserted along the inferior aspect of the tracheotomy tract and marked at the location of the cervical skin. The manufacturer can then customize the tracheal cannula to fit the patient. By removing one or more rings of the cannula, the smooth portion can be customized to fit different stoma lengths (Fig 11).

Some patients have been able to remove, clean, and reinsert their cannulas with ease; for them, cannula care is greatly simplified (Fig 15). Removal and reinsertion should only be performed by physicians familiar with the use of this device, unless the patient is properly trained by the physician.

SPECIAL FEATURES

Short-Term Cannula. There are 10 circumferential rings on the shaft of the tracheal cannula. The three inner rings are in the shape of circumferential barbs. This design allows the tracheal cannula to be easily inserted, but prevents it from being anteriorly displaced once it is fixed in place (Fig 10B). The remaining rings are rounded. The grooves between these ridges serve to secure the faceplate or ring washer in the desired position according to the distance between the anterior tracheal wall and the surface of the anterior cervical skin.

The wing-shaped faceplate secures the cannula in place at the time of operation. It is sutured to the skin with 3-0 monofilament suture material. The plug is used to obstruct the cannula when the cannula airway is not needed. It is fixed in place simply by inserting and twisting it in a clockwise direction. The plug has a head so that it cannot be introduced too far into the tracheal cannula. After the silicone tracheal cannula has been in place for a week, the wing-shaped faceplate can be replaced by the ring washer. The ring washer is less bulky and prevents irritation of the skin surrounding the cannula.

Long-Term Cannula. The shaft of the long-term cannula between the inner flange and the first outer ring has a highly polished surface (Fig 16B). This surface permits and encourages growth of epithelium from both the trachea and the skin so as to line the tissue of the tracheotomy tract.

Two ring washers are supplied with the long-term silicone tracheal cannula. These washers can be placed in various positions, depending on the distance between the anterior tracheal wall and the surface of the anterior cervical skin, and are necessary to maintain the position of the inner flange against the anterior tracheal wall. The plug is used in patients who require a tracheotomy intermittently. A patient with sleep apnea, for example, would use this plug during waking hours and remove it at night for sleep.

Extralong Cannula. The Montgomery extralong long-term cannula has been designed for use in obese or pickwickian patients with sleep apnea or who require a long-term airway. Its unique design allows for easier insertion, less incidence of granulation tissue formation, and gradual epithelialization

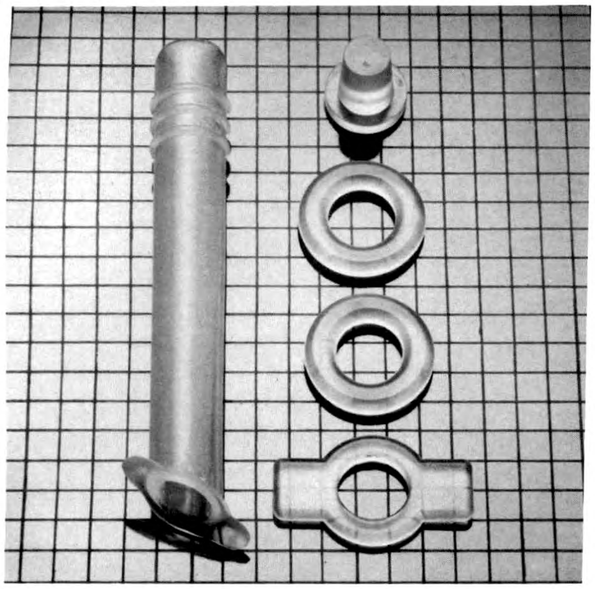


Fig 17. Extralong tracheal cannula shown with ring washers, faceplate, and plug.

of the tracheotomy tract (Fig 17). The extralong cannula can be shortened to the desired length and either plugged or used with a speaking valve. The extralong cannula is supplied with two ring washers, one plug, and a faceplate that can be used to secure the cannula in place.

Size 8 and 10 Custom Cannulas. The Montgomery tracheal cannulas in sizes 8 and 10 are designed for patients who require greater airflow through the tracheotomy stoma. The versatile design allows customization of the tube to fit a tracheotomy tract of virtually any length (Fig 18). By removing one or more rings, the smooth portion of the cannula can be increased to fit the patient's stoma length. A stoma measuring kit is available from the manufacturer.

Inner Cannula. An inner cannula is available for all tracheal cannulas to facilitate cleaning and maintenance. This is especially helpful for patients who must keep the cannula plugged during waking hours. The inner cannula is simply twisted and removed for easy cleaning. The inner cannula also has a 15-mm cylinder end to accommodate artificial humidification devices and speaking valves.

Speaking Valves. Special one-way valves have been designed for use with Montgomery Safe-T-Tubes in cases in which the airway is narrowed above the upper intraluminal limb of the Safe-T-Tube and with Montgomery Silicone Tracheal Cannulas in patients with insufficient inspiratory airflow and adequate expiratory airflow (Fig 19). An example of this is a patient with bilateral vocal cord paralysis in the position of adduction.

The valve is applied to the Safe-T-Tube or cannula by being attached over the last ring on the external end, which has been shortened to the desired length (Fig 20). It is held in place by four prongs that fit over the trimmed end.

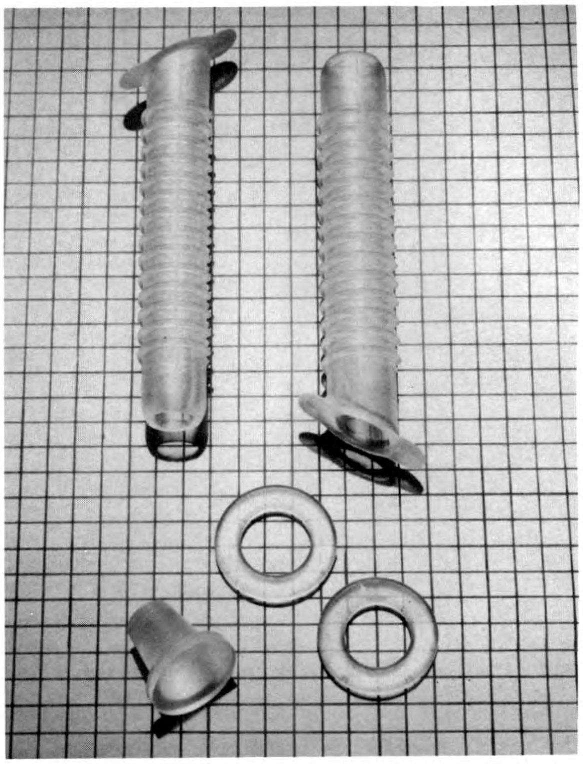


Fig 18. Size 8 and 10 cannulas.

The valve mechanism consists of a very thin silicone diaphragm that opens inward during inspiration and closes against the inside of the anterior aspect of the valve housing during expiration. During forceful expiration such as coughing, the diaphragm of the valve releases excess pressure by partially extruding from the anterior end of the valve housing. The diaphragm of the valve is very easily reengaged into the normal functioning position by an index finger placed against the end of the valve housing.

In addition to the cough release feature, the speaking valve has other advantages over previous tracheotomy valves. During inspiration it allows for sufficient airflow even during strenuous exercise. The valve is silent as it functions, in contrast to the very noisy clicking sound of the metallic tracheotomy valves. A speaking valve for standard tracheotomy tubes with a 15-mm end is also available (Fig 19A).

ATTACHMENT OF SPEAKING VALVE

Several rings should be left on the tracheal cannula or Safe-T-Tube to allow for grasping the tube while attaching or removing the speaking valve. To ensure a snug fit and reduce potential air leakage, make sure the end of the tube has been trimmed flush with the last remaining ring. With one hand, grasp the exterior end of the cannula or Safe-T-Tube to prevent movement of the tube. With the

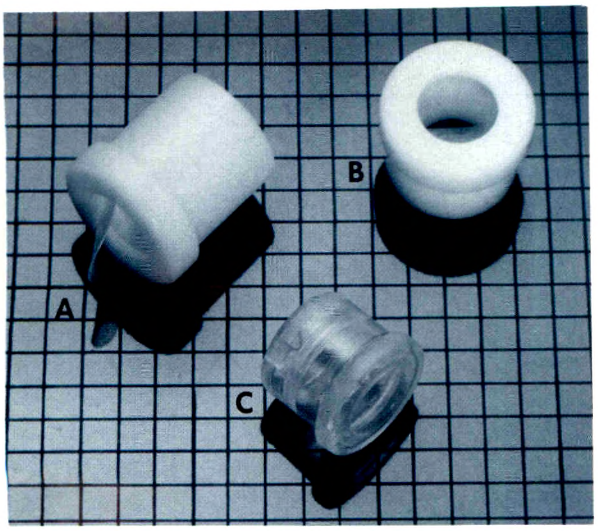


Fig 19. Speaking valves for standard tracheotomy tubes (A) and Safe-T-Tube and silicone tracheal cannula (B,C).

other hand, hold the valve at a slight angle, pressing the base on the end of the tube and rotating the valve toward the neck (Fig 20A). If using the valve model for standard tracheotomy tubes, press and rotate the valve on the 15-mm end of the tube.

RESETTING VALVE DIAPHRAGM AFTER RELEASE

When the silicone diaphragm has been released by a cough or excessive airway pressure, simply press the diaphragm back into the valve housing with the tip of your finger. Normal valve operation will resume.

REMOVAL OF SPEAKING VALVE

For cannula and Safe-T-Tube valve models, it is best to remove the valve with a slight twist (Fig 20B). The valve model for standard tracheotomy tubes is simply rotated off.

CLEANING THE VALVE

The silicone diaphragm of the speaking valve is a delicate device. To prevent damage to the mechanism, care should be taken when cleaning the valve. The best method for cleaning the speaking valve is to use warm soapy water and cotton-tipped applicators. Submerge the valve in the soapy solution and allow it to soak for a few minutes to loosen any substance inside the valve. Clean the inside of the valve using the applicators, being very careful not to damage the delicate silicone diaphragm. Continue this procedure until the valve is clean. Rinse the valve thoroughly under running water until the detergent is completely washed away. Allow the valve to dry before using it.

CARE OF CANNULA

Postoperative Care. The faceplate is left in place for 7 to 10 days or until the short-term tracheal cannula is secured in place and the tracheotomy incision is healed. It is advisable to clean under the faceplate twice a day with peroxide solution and Betadine solution or ointment. A record is made of the groove into which the faceplate has been inserted.

The small silicone ring washer replaces the faceplate in the same groove when the faceplate is removed (Fig 12M). The cannula can be shortened to a convenient length at this time by simply cutting it with a No. 11 surgical blade or straight scissors. The ring washer helps prevent displacement of the tube and is less irritating to the skin surrounding the tracheostome than the faceplate. After 4 to 6 weeks, the short-term cannula is usually removed and replaced with a long-term tracheal cannula.

The silicone tracheal cannula may be plugged when it is not needed to assist or replace the upper airway. The plug is inserted with a slight twist.

Postoperatively, a lateral soft tissue x-ray film of the larynx and trachea is obtained to make certain that the inner flange of the cannula is in the proper position and firmly against the inner aspect of the anterior tracheal wall (Fig 21).

Basic Care Instructions.

1. The cannula should remain plugged or have a speaking valve attached whenever possible. This

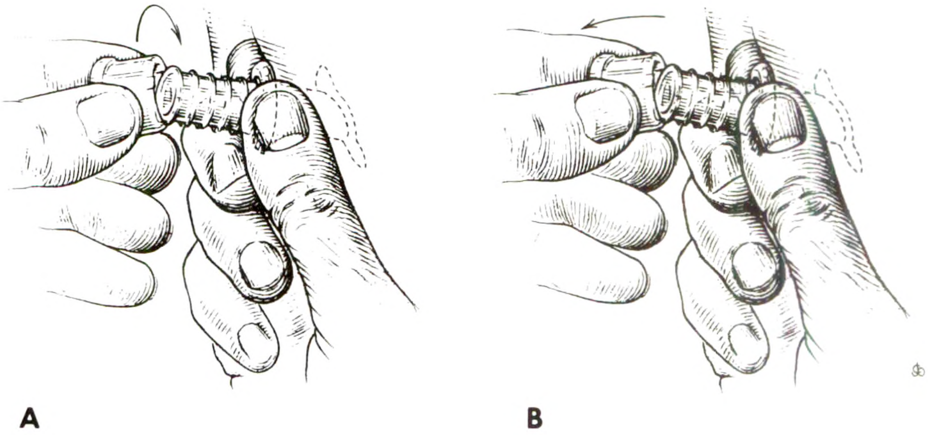


Fig 20. A) Attachment of speaking valve. B) Removal of speaking valve.

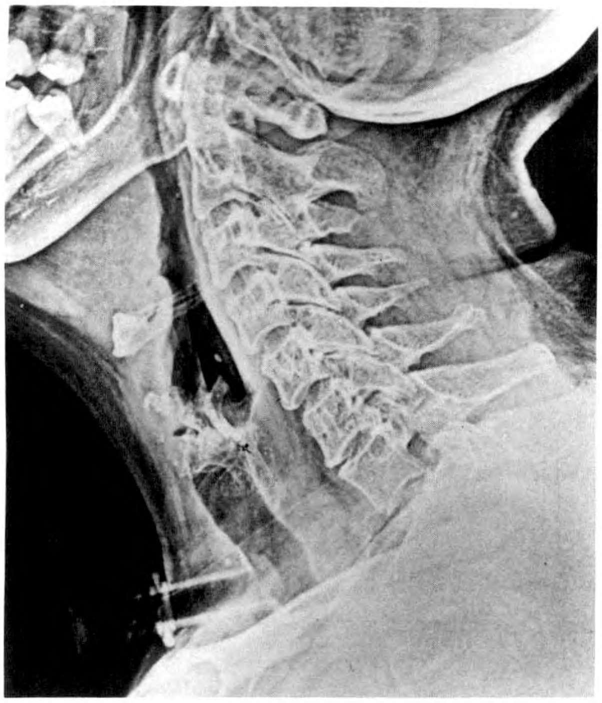


Fig 21. Xeroradiograph of patient showing inner flange of long-term silicone tracheal cannula fitting snugly against anterior intraluminal trachea. Note lack of ridges on cannula between trachea and skin. Film also demonstrates advantage of 27° angle of flange to long axis of cannula.

will help keep the trachea moist and allow for normal respiration and phonation.

2. Before cleaning, remove the plug. To prevent misplacement of the plug, make a necklace (suture or dental floss material) or use a plug holder from the manufacturer.
3. Use the following items: cotton-tipped applicators, hydrogen peroxide solution, and normal saline solution. Clean the inside and outside of the cannula with an applicator dipped in hydrogen peroxide solution. Use suction if necessary to clean the inside of the cannula. Using an applicator dipped in saline solution, continue to clean until no hydrogen peroxide is left on the applicator and the inside of the cannula is clear. Sodium bicarbonate (5%, 2 mL) may be necessary to loosen thick mucus inside the cannula.
4. Clean the skin around the external portion of the cannula twice daily; remove crusts; apply Betadine solution or Aureomycin (chlortetracycline HCl 3%) ointment as directed by the physician.
5. Constant humidity is recommended during the winter months and if persistent crusting occurs inside the cannula.

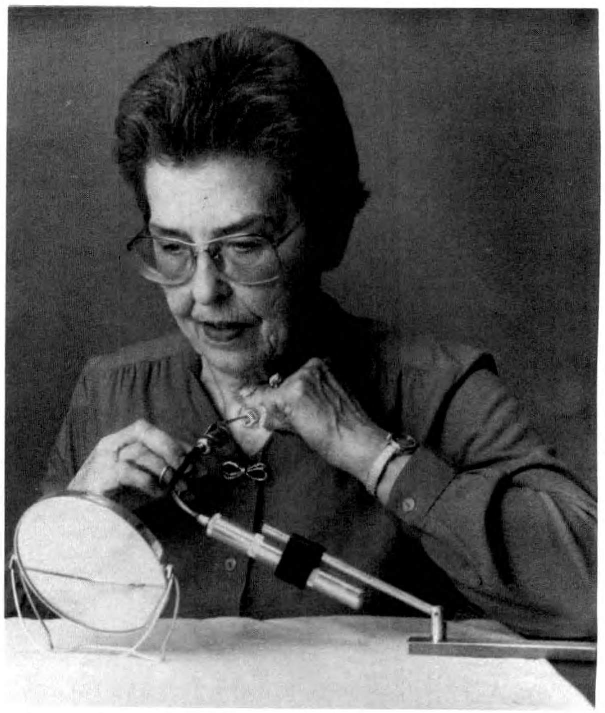


Fig 22. Home care method for cleaning cannula. (Courtesy Nell L. Deaver.)

Home Care Cleaning.

The following instructions are from N. L. Deaver (personal communication, 1989).

1. Equipment: mirror on stand, light source, alligator forceps, and suction machine.
2. Place the mirror and light on a counter or tabletop.
3. Set up the suction machine so that the tip is readily available.
4. While seated, adjust the mirror and light source so that an adequate view of the inside of the cannula is possible. It is best to be able to see the internal end of the cannula to help prevent touching the posterior wall of the trachea while cleaning.
5. Carefully insert the end of the forceps (with forceps in closed position) into the cannula. Carefully manipulate the forceps to grasp and withdraw any crusts or mucous plugs (Fig 22). Use suction as necessary to remove smaller pieces.
6. Repeat until the inside of the cannula is clear.
7. Clean the skin around the external portion of the cannula twice daily; remove crusts; apply Betadine solution or Aureomycin (chlortetracycline HCl 3%) ointment as directed by physician.

MONTGOMERY SALIVARY BYPASS TUBE

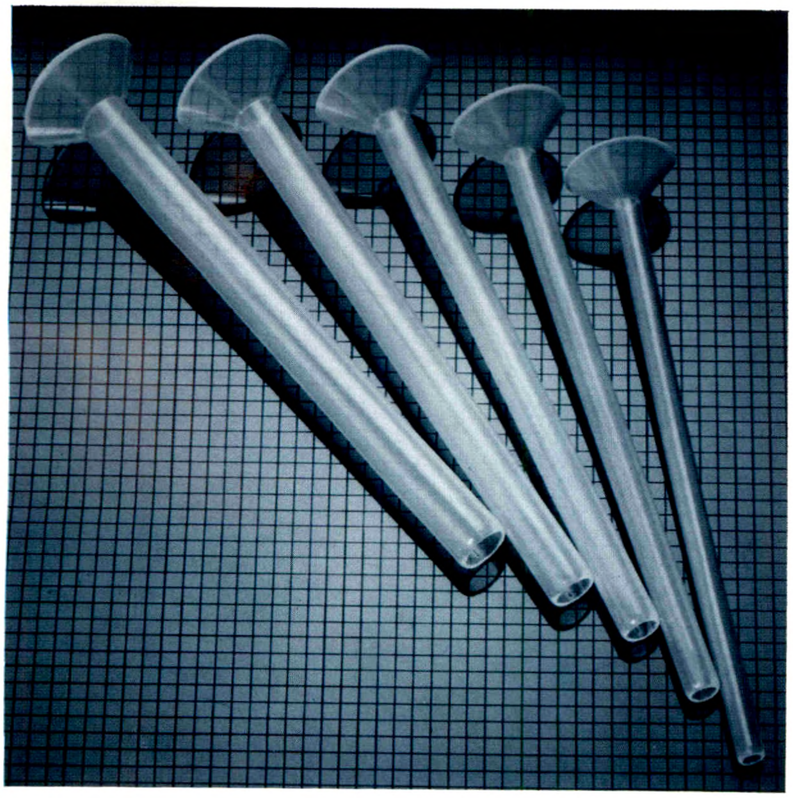


Fig 23. Salivary bypass tubes.

DESCRIPTION

The Montgomery Salivary Bypass Tube (Fig 23) facilitates the management of cervical esophageal and hypopharyngeal strictures and fistulas resulting from a variety of causes including advanced malignancy, surgery, irradiation, trauma, and caustic ingestion.[1] Impending fistulas and strictures may be prevented by timely insertion of these tubes. Established strictures may be treated by tube placement alone or following bougienage dilation. Bypass tubes may be used to stent an esophageal repair of a stricture or tracheoesophageal or esophagocutaneous fistula.

The constant bathing by saliva of tissues that have been altered by surgery, infection, or radiotherapy is a prime factor in retarding the progress of healing and fistula closure. The salivary bypass tube directs saliva into the distal esophagus and allows for spontaneous closure of the fistula, or at least permits the tissue to recover sufficiently to be a suitable recipient for a more formidable measure such as repair using pedicled skin flap tissue.

The Montgomery Salivary Bypass Tube is available in seven sizes: 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, and 20 mm (outside diameter). It is constructed of medical grade silicone, which produces little or no tissue reaction. The tubes are soft and flexible to ensure an optimal fit and to minimize injury to soft tissues; however, they are firm enough to maintain luminal patency in areas of stricture. All of the tubes have an improved funnel-shaped superior end that aids in the collection of saliva and helps to maintain proper positioning of the tube.

INDICATIONS FOR USE

Pharyngocutaneous Fistulas Following Laryngectomy or Laryngoesophagectomy. As a general rule, postlaryngectomy and postlaryngoesophagectomy fistulas have been treated with iodoform gauze packing that has been impregnated with either Betadine solution or Aureomycin ointment, along with cumbersome dressings. The use of the salivary bypass tube has greatly reduced the healing time of these fistulas by diverting the saliva into the distal esophagus. It is our preference to leave a nasogastric feeding tube in place for 7 days following a total laryngectomy or laryngoesophagectomy (10 days if the patient has received radiotherapy). At the end of this period, a barium swallow examination is done to make certain that there is no break in the hypopharyngeal or esophageal repair, with a resultant sinus tract or pharyngocutaneous fistula, be-

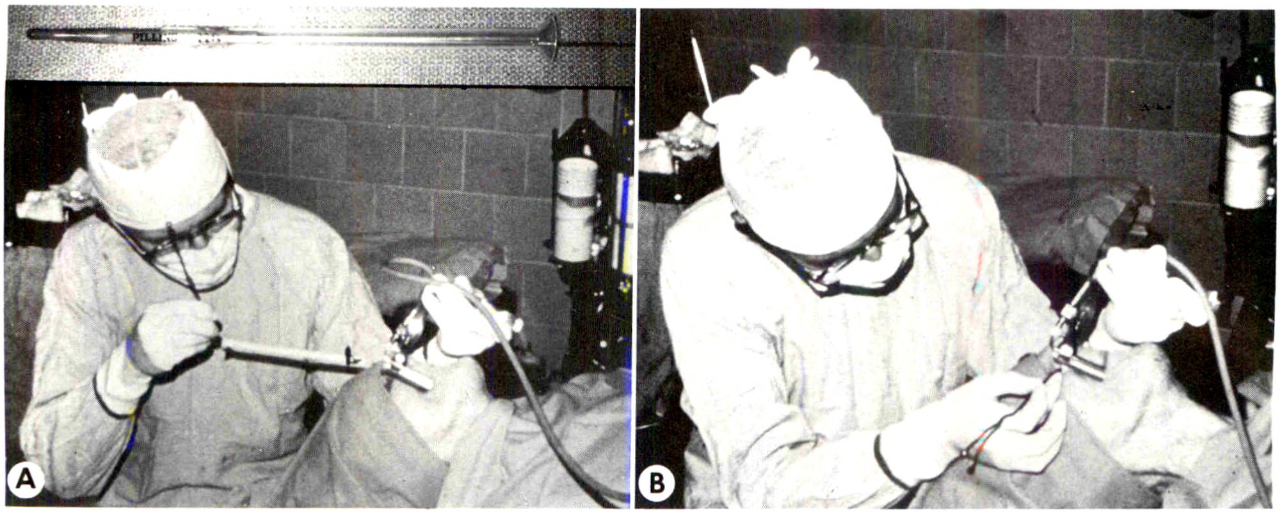


Fig 24. Procedure for inserting salivary bypass tube. A) Standard Jackson laryngoscope is used to expose hypopharynx. Endotracheal tube stylet has been inserted into bypass tube, which is crimped at proximal end. Inset) Salivary bypass tube inserted over lubricated 22F filiform bougie (often simplest way to insert salivary bypass tube when treating stricture of cervical esophagus). B) Salivary bypass tube inserted into cervical esophagus. At this point stylet and laryngoscope are removed. Upper end of bypass tube is pushed into place with index finger.

fore removing the nasogastric feeding tube and allowing the patient to eat soft foods. If a fistula is impending or present, the nasogastric feeding tube is removed and a salivary bypass tube (usually the 14-mm size) is inserted with the nasogastric tube, thus preventing or treating the fistula before it becomes a clinical problem. After an additional week or 10 days, the tubes are removed and another barium swallow study is performed. Almost invariably the problem resolves at this point. A lateral neck x-ray study is done to make certain that the salivary bypass tube has been properly placed.

Esophageal Fistulas in Advanced Cancer of Pharynx or Cervical or Thoracic Esophagus With Dysphagia. A case of advanced cancer may be further complicated by a pharyngocutaneous fistula if the patient has undergone laryngectomy or laryngoesophagectomy. A nasogastric feeding tube or gastrostomy is needed for nourishment. The insertion of a salivary bypass tube will serve to control the saliva and allow the patient to swallow liquids and a semisolid diet, provided a 12- or 14-mm tube has been used.

Stricture of Cervical Esophagus. A stricture of the hypopharynx or cervical esophagus is a common complication following ingestion of caustic material. The insertion of a salivary bypass tube can prevent such a stricture if it is inserted at a reasonable length of time following the burn. The stricture is dilated with bougienage before insertion of the salivary bypass tube. Often in these cases a nasogastric tube fixed to the salivary bypass tube is not necessary because patients can nourish themselves through the bypass tube, and there is little danger that the bypass tube will become displaced into the distal esophagus and stomach. When a stricture of the cervical esophagus is being treated, the bypass tube should remain in place for at least 3 weeks.

Tracheoesophageal Fistula. The salivary bypass tube serves to stent tracheoesophageal fistula repair while also preventing or treating stricture of the cervical esophagus.

Reconstruction of Cervical Esophagus. The salivary bypass tube is used during reconstruction of the cervical esophagus with a pectoralis major myocutaneous flap in order to prevent fistula formation and strictures that usually occur at the upper or lower anastomoses.

Lesions of Lower Esophagus. The salivary bypass tube has been successfully used as a palliative measure with carcinoma of the middle and lower thirds of the esophagus. The presence of the bypass tube allows the patient to control saliva and also ingest a liquid or semisolid diet. The silicone salivary bypass tube can remain in place while these lesions are being treated with radiotherapy.

INSERTION

The salivary bypass tube is best inserted under general anesthesia and with direct vision using a Jackson laryngoscope such as that used by the anesthesiologist (Fig 24A). The tube can be inserted by folding up the distal end and grasping it with alligator-type endoscopic forceps. McGill forceps and an endotracheal tube stylet can be of value when one is inserting a salivary bypass tube. A Jackson laryngoscope is used to expose the hypopharynx. An endotracheal tube stylet is inserted through the salivary bypass tube. The salivary bypass tube is inserted into the laryngoscope and cervical esophagus. The laryngoscope and stylet are removed, and the funnel-shaped upper end of the salivary bypass tube is pushed in place with the index finger (Fig 24B).

TABLE 2. SIZES OF SALIVARY BYPASS TUBES AND NASOGASTRIC FEEDING TUBES

Outside Diameter of Bypass Tube (mm)	*Feeding Tube No.*
8	10
10	12
12	14
14	14
16	14-16
18	14-16
20	14-16

A stricture of the cervical esophagus is dilated with bougies of increasing diameter. When the maximum bougie size is determined, a bypass tube is selected that will fit loosely over a slightly smaller bougie. The bougie is well lubricated before it is inserted into the bypass tube so that it can be easily removed once the bypass tube is in place (Fig 24A, inset). Once the bougie has been removed, an index finger inserted into the funnel portion of the bypass tube pushes its upper end into place in the pharynx.

It is imperative that the largest possible size of bypass tube be used so that the tube will not pass into the stomach. If the surgeon is concerned about this possibility or if a nasogastric feeding tube is to be used, then the feeding tube is inserted along with the salivary bypass tube. The suggested size of nasogastric feeding tube for each size of salivary bypass tube is indicated in Table 2. To accomplish the insertion, an estimate of the length between the upper cervical region and the stomach is made, and a mark is placed on both the nasogastric feeding tube and the salivary bypass tube at a point at which a suture will be placed (Fig 25A). The feeding tube is then passed into the nasal cavity and out of the mouth (Fig 25B). The feeding tube is inserted through the bypass tube until the mark on the feeding tube matches that on the bypass tube. The feeding tube is fixed to the bypass tube with one or two nonabsorbable sutures. The suture(s) is passed

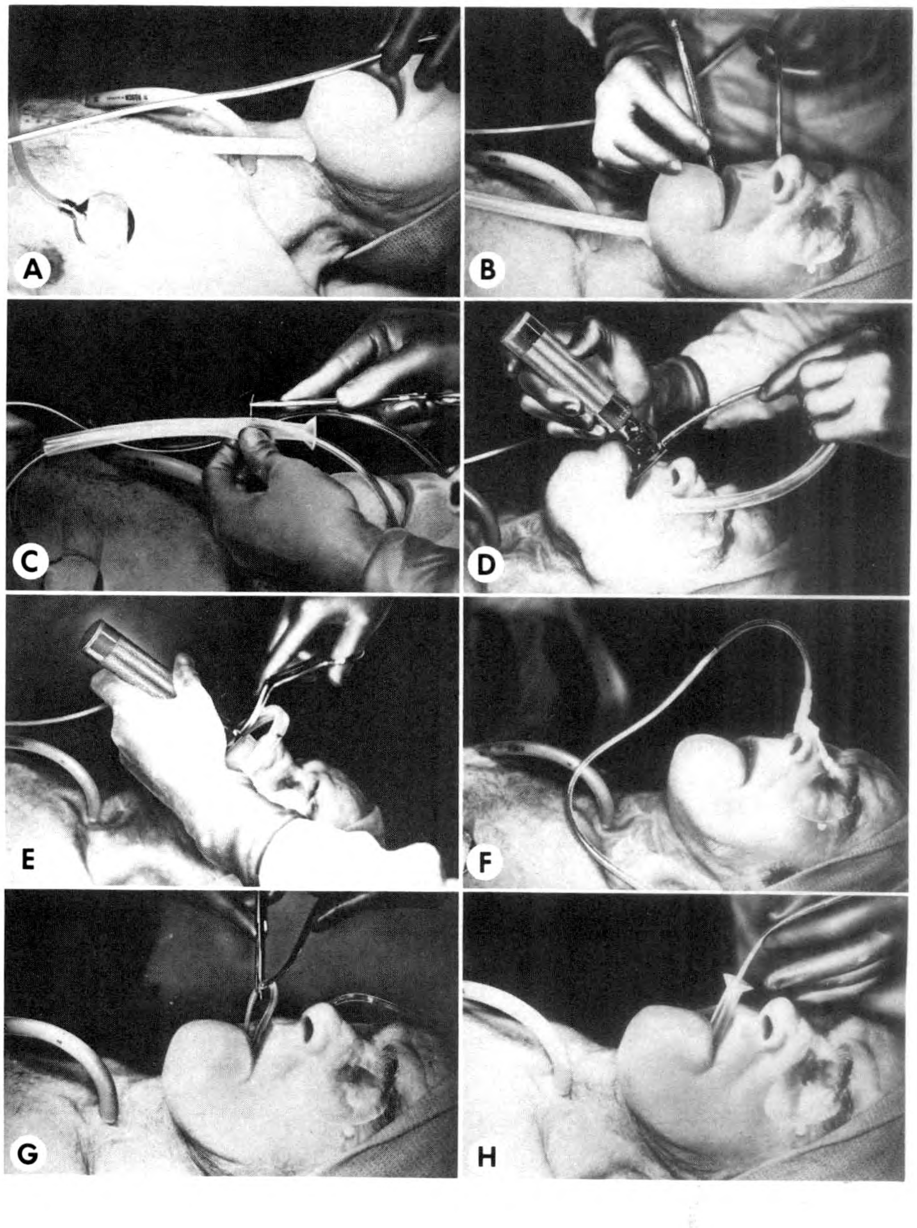


Fig 25. Method for attaching salivary bypass tube to nasogastric feeding tube. A) Feeding tube is placed over chest down to point several centimeters below xiphoid process. Salivary bypass tube is placed over cervical region. Mark is made on both salivary bypass tube and feeding tube at points at which they will be sutured together. B) Nasogastric feeding tube is inserted into nasal cavity, nasopharynx, and oropharynx and out of mouth. C) Salivary bypass tube is inserted over feeding tube. Two marks are matched, and suture is placed through wall of bypass tube around feeding tube and out through wall of bypass tube. Second suture may be placed for additional security. D) Feeding tube is inserted into cervical esophagus. E) Anesthesia scope and McGill forceps are used to insert salivary bypass tube. F) Feeding tube is securely fastened to nose with either adhesive tape or suture. G) To remove salivary bypass tube, feeding tube is grasped in oropharynx and loop pulled out of mouth. This loop of feeding tube is cut. H) Upper portion of feeding tube has been removed from nose, and bypass tube and distal portion of feeding tube are pulled from mouth.

through the wall of the bypass tube around the feeding tube and out through the wall of the bypass tube (Fig 25C). The feeding tube and the salivary bypass tube are inserted into the esophagus (Fig 25D,E). The nasogastric feeding tube is securely fastened to the nose (Fig 25F).

REMOVAL

The salivary bypass tube can be removed with or without anesthesia, depending on whether or not esophagoscopy is to be carried out at the same time. The feeding tube is grasped in the pharynx and pulled out the mouth until the upper end of the nasogastric feeding tube can be visualized (Fig 25G). The feeding tube is cut as it loops out from the mouth, and the upper portion of the feeding tube is removed from the nose. The bypass tube and the distal portion of the feeding tube are removed from the mouth (Fig 25H).

MONTGOMERY ESOPHAGEAL TUBE

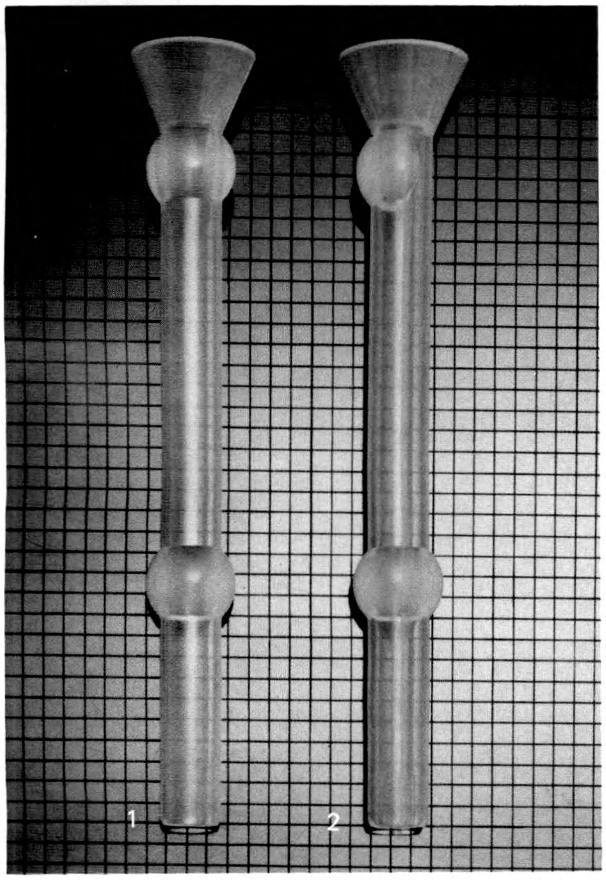


Fig 26. Silicone esophageal tube used to bridge gap between pharyngostome and esophagostome following laryngoesophagectomy and in cases of untreatable carcinoma involving large defect between pharynx and lower esophagus. 1 — anterior view, 2 — posterior view.

DESCRIPTION

A specially designed esophageal tube is used between the first and second stages of reconstruction of the cervical esophagus (Fig 26). This tube is made of medical grade silicone and has an outside diameter of 15 mm. Its upper, funnel-shaped end fits into the pharynx and prevents downward displacement of the tube. The bulbous dilation just below the upper, flared end is situated inferior to the pharyngostome and prevents upward displacement of the tube. The lower, dilated portion of the tube is situated below the esophagostome and assists in preventing reflux of the gastric contents into the cervical region.

INDICATIONS FOR USE

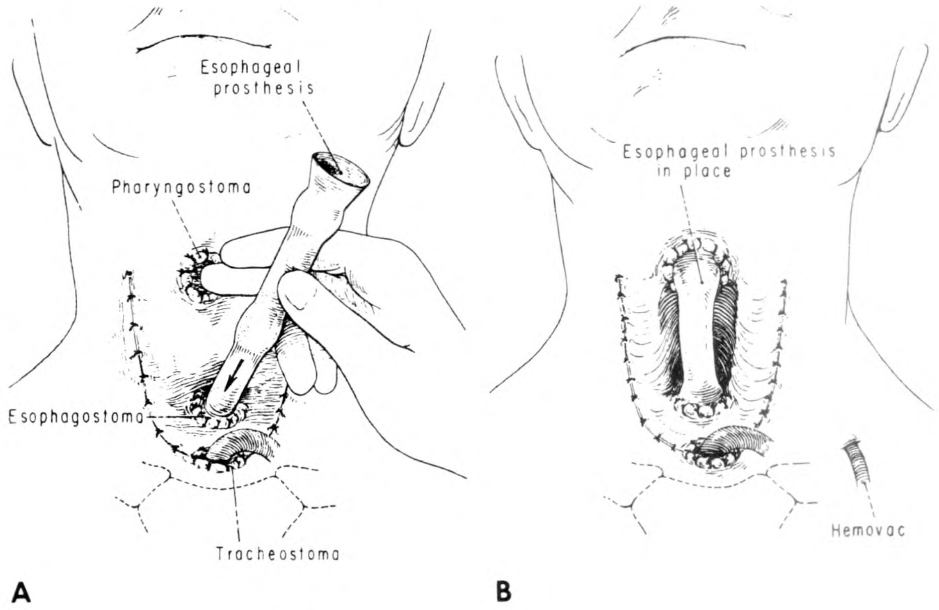
This tube has been designed specifically for use in reconstructive surgery of the cervical esophagus. It is used to bridge the gap between the pharyngostome and the esophagostome following laryngoesophagectomy and first-stage reconstruction of the cervical esophagus.

METHOD FOR USE

After completion of the first-stage operation, the tube is inserted into the esophagostome and then into the pharyngostome (Fig 27[3]). Once it is in place, suturing is not necessary. The esophageal tube has three functions.

1. It tends to eliminate the problem of profuse salivary leakage by way of the pharyngostome. (A few patients have been able to eat and drink with

Fig 27. Silicone esophageal tube is first inserted A) into esophagus and then B) up into pharynx. (Reprinted with permission.[3])



the tube in place.)

2. It maintains a widely patent pharyngostome and esophagostome. (We know of no instance of postoperative stenosis following the use of the esophageal stent.)
3. It creates a trough between the pharyngostome and the esophagostome, thus facilitating the second-stage procedure.

The esophageal tube remains in place for 4 to 6 weeks, at which time the second-stage reconstruction of the cervical esophagus is accomplished. Some surgeons prefer to insert a salivary bypass tube along the feeding tube when performing the second-stage reconstruction.

Complete details of these reconstructive procedures can be found in Volume 2 of *Surgery of the Upper Respiratory System.*[3]

MONTGOMERY LARYNGEAL STENT

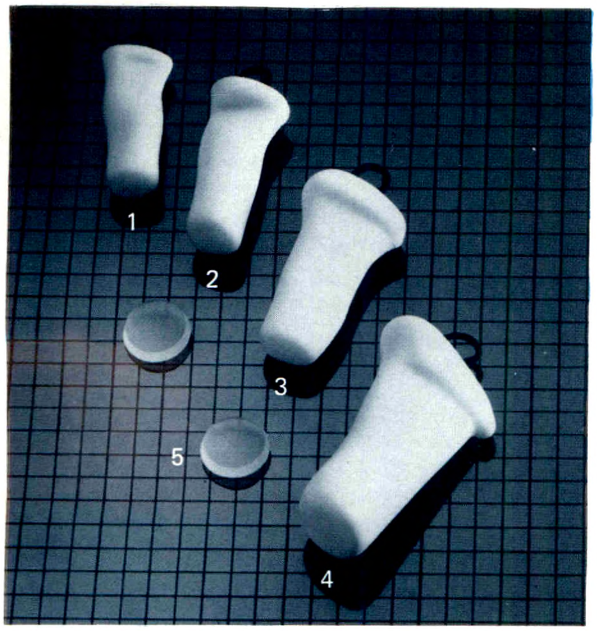


Fig 28. Laryngeal stent, designed to conform to normal endolaryngeal surface, shown in four sizes. 1 — child size, 2 — small adult size, 3 — medium adult size, 4 — large adult size, 5 — silicone buttons to support stent externally.

DESCRIPTION

The Montgomery Laryngeal Stent is a molded silicone prosthesis designed to conform to the normal endolaryngeal surface (Fig 28). The stent is constructed of a medical grade silicone material that is firm enough to support the endolarynx postoperatively after laryngoplasty and is soft and flexible enough to ensure a conforming fit while minimizing injury to soft tissues. The silicone material produces little or no tissue reaction and allows re-epithelialization of the endolaryngeal mucosa. In addition, the laryngeal stent may be used as a direct support for intralaryngeal mucosa or dermal grafts to denuded areas of the endolarynx. The laryngeal stent is available in four sizes: child, small adult, medium adult, and large adult.

INDICATIONS FOR USE

The laryngeal stent is indicated in the prevention and treatment of laryngeal stenosis when the glottic stenosis involves the midglottis, posterior glottis, supraglottis, and subglottis, singularly or in combination with a Safe-T-Tube. The stent may be used in the following situations: 1) with repair of simple glottic stenosis involving the middle or posterior aspect of the true vocal cords; 2) with repair of more complicated laryngeal stenosis involving the glottis, supraglottis, and subglottis (eg, following severe laryngeal trauma); 3) to facilitate endolaryngeal grafting (eg, utilizing free mucosal or split thickness skin grafts); and 4) to prevent endolaryngeal stenosis in situations in which glottic, supraglottic, or subglottic stenosis is likely to occur (eg, following extralaryngeal or endolaryngeal trauma with significant interruption of the endolaryngeal mucosa).

The stent should remain in place from 3 to 8 weeks following laryngeal reconstruction, depending upon the severity of the injury and the extent of the repair. When treating a patient with complete laryngeal stenosis involving the anterior commissure, it is best to use a silicone keel (p 27) for 2 weeks following removal of the stent to ensure reformation of a sharp anterior commissure and to prevent the formation of an anterior web. In such cases, the silicone stent is removed by way of laryngofissure rather than by direct laryngoscopy.

INSERTION

Preoperative, intraoperative, and postoperative

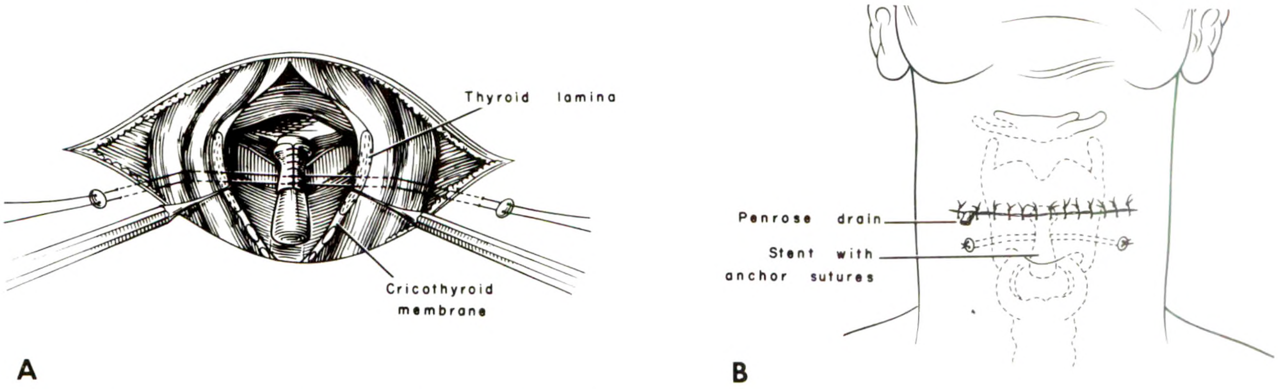


Fig 29. Insertion of laryngeal stent. A) Mucosal or skin graft-covered silicone stent inserted into larynx and secured with two 3-0 monofilament sutures. B) Postoperative site. Suture material is supported externally by silicone buttons. Penrose drain has been inserted but will be removed on second postoperative day. (Reprinted with permission.[3])

coverage with appropriate antibiotics is indicated. The laryngeal stent is inserted by a standard midline laryngofissure technique after preoperative radiographs and direct laryngoscopy have determined the location and extent of the stenosis.

After removal of obstructing scar tissue and advancement of intralaryngeal mucosa to cover mucosal defects, the laryngeal stent is inserted and secured in place with two sutures of 3-0 nylon tied over a silicone button on each side of the neck (Fig 29[3]). If a large mucosal defect remains after the endolaryngeal stenosis has been resected, a split thickness skin graft or a mucosal graft from the nasal septum or buccal mucosa should be appropriately positioned on the laryngeal stent and sutured to the larynx so as to cover the defect. The surgeon may prefer to suture the graft to the laryngeal defect rather than to the stent.

REMOVAL

The laryngeal stent must be used in conjunction with a tracheotomy. It may be removed approximately 4 to 8 weeks following insertion. If the original laryngeal stenosis did not involve the anterior commissure and there is little likelihood of the patient's developing an anterior glottic stenosis, the laryngeal stent may be removed endoscopically under general anesthesia. After removal of the percutaneous anchor sutures, the laryngeal stent is removed with sustained, gentle traction applied superiorly through or along with a laryngoscope. This maneuver is accomplished by grasping the black silk suture loop on the superior surface of the stent with a toothed laryngeal alligator forceps and slowly disengaging the stent into the hypopharynx under direct vision. Care should be taken to avoid dislocating the arytenoid cartilages or producing mucosal lacerations during stent removal. Following endoscopic stent removal, direct laryngoscopy should be performed to document the status of healing of endolaryngeal structures.

The laryngeal stent should be removed by the standard laryngofissure technique if 1) the stent cannot be removed easily endoscopically as described above or 2) there is significant likelihood that an anterior glottic stenosis will occur following stent removal. If laryngofissure is used, then a Montgomery Laryngeal Keel (p 27) is inserted intraoperatively after stent removal and before laryngeal closure to prevent the postoperative occurrence of anterior laryngeal stenosis.

MONTGOMERY LARYNGEAL KEEL

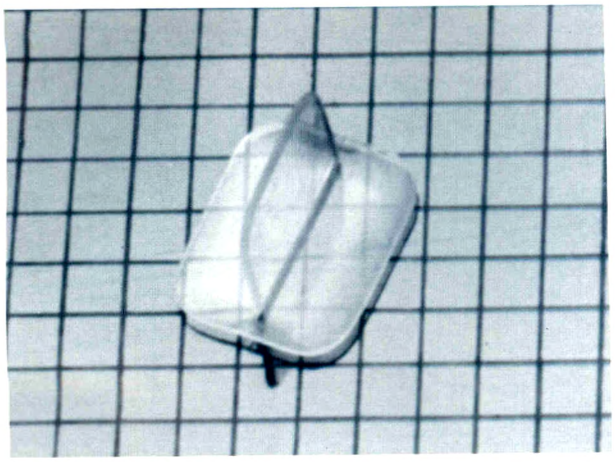


Fig 30. Laryngeal keel is umbrella-shaped prosthesis designed to prevent and treat anterior laryngeal stenosis.

DESCRIPTION

The Montgomery Laryngeal Keel is an umbrella-shaped prosthesis designed to prevent and treat anterior laryngeal stenosis (Fig 30). The keel is constructed of medical grade silicone material that produces no tissue reaction. It is soft and flexible to ensure a conforming fit and to minimize injury to soft tissue; however, the keel is firm enough to prevent stenosis of the anterior vocal cord commissure. The keel is available in two sizes and may be trimmed to a smaller size for pediatric patients.

INDICATIONS FOR USE

The laryngeal keel is indicated in the prevention and treatment of laryngeal stenosis when the glottic stenosis is limited to the anterior commissure of the vocal cords. The keel may be used in the following situations: 1) to repair simple anterior glottic stenosis due to anterior commissure web formation, 2) to prevent anterior glottic stenosis in situations in which anterior commissure stenosis is likely to occur (eg, following extralaryngeal or endolaryngeal trauma with loss of anterior commissure), and 3) to prevent anterior glottic stenosis immediately following removal of a laryngeal stent.

INSERTION

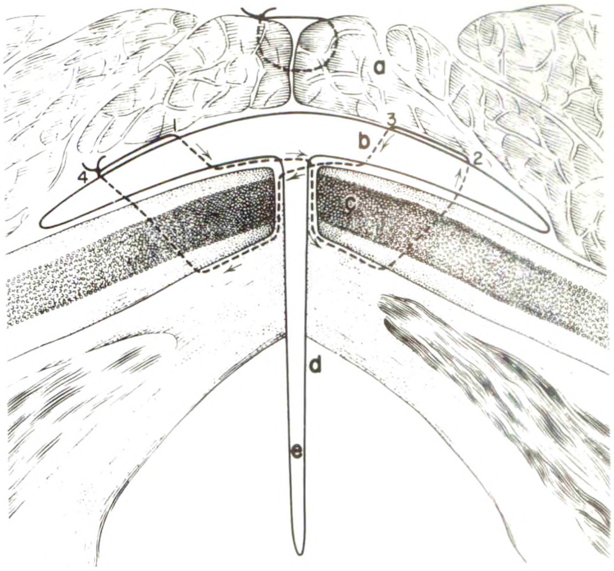


Fig 31. Insertion of laryngeal keel. Tight closure of thyroid laminae and fixation of silicone keel are best accomplished by use of figure eight suture (4-0 monofilament). Suture is first placed through extralaryngeal portion of keel (1) and then through base of intralaryngeal extension. Suture is continued through thyroid laminae and extralaryngeal portion of keel on opposite side (2). Second half of suture (3,4) is placed in direction reverse to that of first half. Figure eight sutures must be completed before insertion of keel. Sutures are placed in thyroid laminae above and below keel, and sternohyoid muscles are approximated in midline over keel. a — sternohyoid muscles, b — extralaryngeal portion of keel, c — thyroid laminae, d — anterior commissure, e — intralaryngeal portion of keel. (Reprinted with permission.[3])

Preoperative, intraoperative, and postoperative coverage with appropriate antibiotics is indicated. Most often, the site of the anterior glottic stenosis can be approached from below, provided the stenosis is not extensive and the dissection has been carried out in the exact midline, where the area can then be precisely incised with a button knife. When dealing with extensive stenosis, it is best to split the stenosis under direct vision through a laryngoscope, prior to performing the laryngofissure. On occasion, the site of an anterior glottic stenosis is best approached from above through the thyrohyoid membrane. The silicone keel is fixed in place with two figure eight sutures of 4-0 monofilament suture material (Fig 31[3]). Both knots should be placed on the same side of the keel. This procedure should be recorded so the sutures can be easily identified at the time of removal. The thyroid laminae, thyrohyoid muscles, and cricothyroid membrane are approximated above and below the keel. The sternohyoid muscles are sutured together over the extralaryngeal portion of the keel.

REMOVAL

Re-epithelialization of the anterior commissure is usually completed within 14 days of keel insertion, and the keel may therefore be removed 14 to 21 days after insertion. The keel is usually removed with local anesthesia and use of a small anterior neck incision through the overlying soft tissues.

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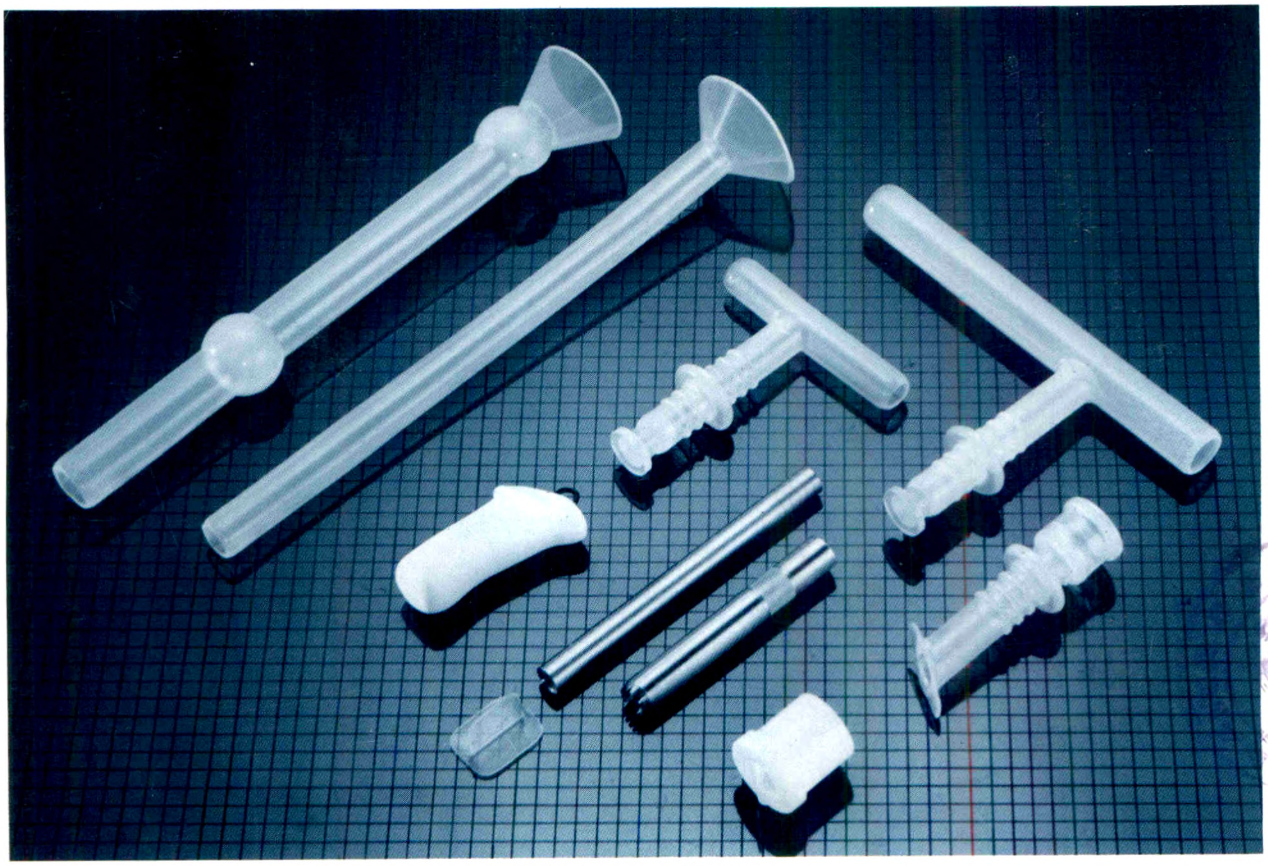

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TEN YEARS OF EXPERIENCE WITH THE SWEDISH BONE-ANCHORED HEARING SYSTEM

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ANNALS
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RHINOLOGY &
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In 1977, a new phase began in hearing rehabilitation of patients with chronic middle and external ear diseases and atresias. Thus far, these patients have had to rely on conventional bone conduction and air conduction devices that for various reasons give poor rehabilitation. The principle of the new treatment, made possible by the Swedish bone-anchored hearing system, is simple: sound vibrations are directly transmitted to the skull bone via a skin-penetrating titanium implant and then are further transmitted to the cochlea, bypassing the middle ear. The present paper summarizes our results in 147 patients over 10 years, including a total of 6,334 follow-up months. No significant rate of skin infections was observed. In over 93% of the observations, no sign of adverse skin reaction was seen. When herein-suggested indications for treatment with the bone-anchored sound processor HC-200 are followed, the success rate is over 90%. The improved quality of life reported by the patients is a combination of improved quality of sound, improved comfort, and relief from middle ear and ear canal disease occasioned by conventional hearing aids.

KEY WORDS — bone-anchored hearing system, hearing rehabilitation, titanium implant.

INTRODUCTION

BACKGROUND

The use of titanium implants for treatment of edentulous patients started in Göteborg, Sweden, in 1965. This was the start of several clinical trials, some of which are still ongoing.[1-4] Brånemark and his team at the Institute of Applied Biotechnology, Göteborg, did the pioneering work on osseointegration and showed that titanium implants can remain stable and reliable for decades in the maxilla and mandible. As of November 1989, more than 330,000 dental implants had been implanted in more than 70,000 patients (U. Lekholm, personal communication, 1989). In a 10-year follow-up study it was noted that the success rates for the implants in the maxilla and the mandible exceeded 80% and 90%, respectively.[4] Titanium implants for the attachment of bone-anchored hearing devices have been in clinical use in Sweden since 1977.[5-10]

CONVENTIONAL BONE CONDUCTION HEARING AIDS

Patients with the diagnoses of chronic otitis media, malformed ears, and conductive or mixed hearing loss are common in clinical otology. Many of these patients have draining ears and almost all have poor hearing. Surgical and/or medical treatment of middle ear disease and conductive hearing loss to obtain a disease-free ear with satisfactory hearing has been performed with increasing success during the past three decades. Such treatment, however, is not successful in all cases, and a sound amplification device is needed to rehabilitate the patient. Patients in need of sound amplification, but who cannot use an air conduction (AC) hearing aid, are candidates for a conventional bone conduction (BC) hearing aid. The principal otologic indications for such a device are 1) chronic otitis media, at times accompanied by external otitis, 2) congenital malformation of the middle or external ear that cannot be surgically corrected, and 3) otosclerosis or tympanosclerosis in certain cases.

Patient discomfort and poor sound quality are common complaints expressed by patients wearing a BC hearing aid. These complaints are explained in more detail below.

Patient Discomfort. The bone conductor must be applied with a steady pressure to the mastoid region of the temporal bone. This force causes, to various degrees, pain, headache, irritation of the skin, and eczema. The fitting of the bone conductor with a steel spring or a headband is often experienced as uncomfortable and unaesthetic. To reduce acoustic feedback from the bone conductor to the microphone, these two parts have to be separated, and hence the device is more cumbersome.

Poor Sound Quality. The quality of the transmitted sound has relatively low fidelity that is due to an effect referred to as soft tissue attenuation. Occasional variations in the quality of the transmitted sound occur for at least two reasons. First, the bone conductor is not applied at exactly the same place each time; and second, in "hearing eye-

---

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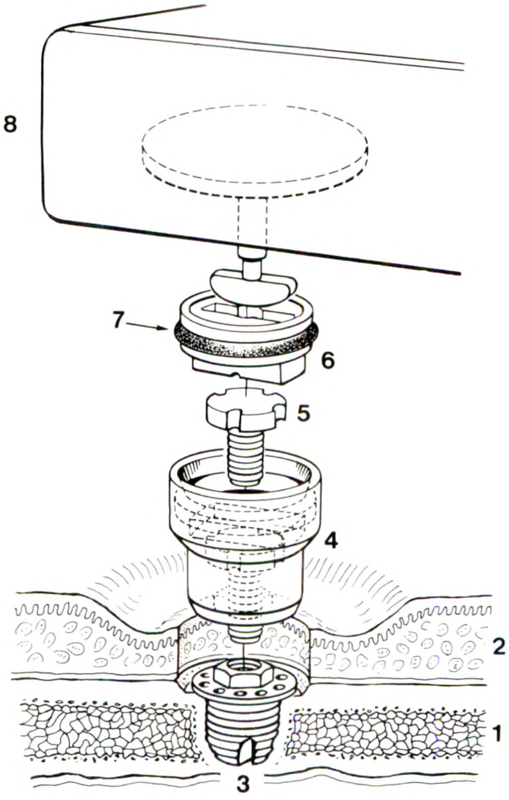


Fig 1. Schematic drawing illustrating direct coupling between sound processor HC-200 and skull. 1) — skull, 2) — skin and subcutaneous tissue, 3) — titanium bone implant, 4) — titanium abutment, 5) — connection screw, 6) — plastic insert, 7) — silicon O-ring, 8) — sound processor HC-200.

glasses" the electroacoustic performance deteriorates with increased operation time because of the flaccidity of the frames.

Some patients with middle ear disease use an AC hearing aid despite a draining ear. It is well known that the occlusive effect of an AC hearing aid earmold, together with the day-long presence of an earmold coated with bacteria from the middle ear infection, militates against cure of the otorrhea in many patients.

NOBELPHARMA AUDITORY SYSTEM

The Swedish bone-anchored hearing system, today commercially available from Nobelpharma AB under the name Nobelpharma Auditory System (NAS), provides a direct bone conduction hearing device for patients with conductive or mixed hearing loss. The NAS consists basically of two parts: an external part, referred to as the sound processor HC-200, and an implanted part, comprising the titanium bone implant and the skin-penetrating titanium abutment. The notation HC-200 is used, in what follows, to denote all sound processors worn by the subjects in the present study, although they are not identical because of some technical modifications. These modifications are discussed in greater detail in Procedure. A more powerful, body-worn version of the HC-200 is commercially available today under the name Superbass HC-220. This model has not been used by any of the patients presented in this study.

The titanium bone implant consists of a threaded cylindrical fixture, made of pure titanium, with a perforated flange at the top of it. Its dimensions are 3.75 mm in diameter and 3.0 or 4.0 mm in depth. As illustrated in Fig 1, the skin-penetrating abutment is firmly fixed to the bone implant with a connection screw. The inside of the abutment is fitted with a plastic insert, which is circumscribed by a silicon O-ring holding the insert in place and serving as a safety release if the HC-200 is exposed to external forces. The vibrator piston of the sound processor fits into a slot in the plastic insert and is coupled by a 90° turning motion.

AIMS OF STUDY

1. To assess the condition of the skin around the skin-penetrating abutment in all subjects.

2. To subjectively assess hearing and comfort with the HC-200 versus the old aid in all subjects.

3. To perform, in a subset of patients, a more detailed investigation in terms of a study of sound field warble tone thresholds in three conditions (HC-200, old aid, and unaided), an evaluation of speech intelligibility in quiet and in noise, and an evaluation of answers to a comprehensive questionnaire about the HC-200.

4. To establish indications and contraindications, based on present results, for treatment with the HC-200, and especially to establish the maximum level of sensorineural hearing loss a patient may have and still be successfully treated by the HC-200.

MATERIAL

SUBJECTS

During the period from 1977 to the beginning of 1987, 147 Swedish subjects underwent titanium implant operations for the Nobelpharma Auditory System at Sahlgren Hospital, Göteborg, Sweden. Seventeen of these subjects also had implant operations on the opposite ear, and 3 were reimplanted on the first side. The present study thus consists of 167 implanted ears, 166 of which were fitted with the HC-200.

No patient has been lost to follow-up. The distribution of age (at the time the abutment was installed) and sex is shown in Fig 2. Most patients were in the age range of 40 to 70 years. Seventy-eight males and 69 females participated in this investigation. The mean age was 50.8 years (SD, 17.4 years); the maximum and minimum ages were 82 and 5 years, respectively.

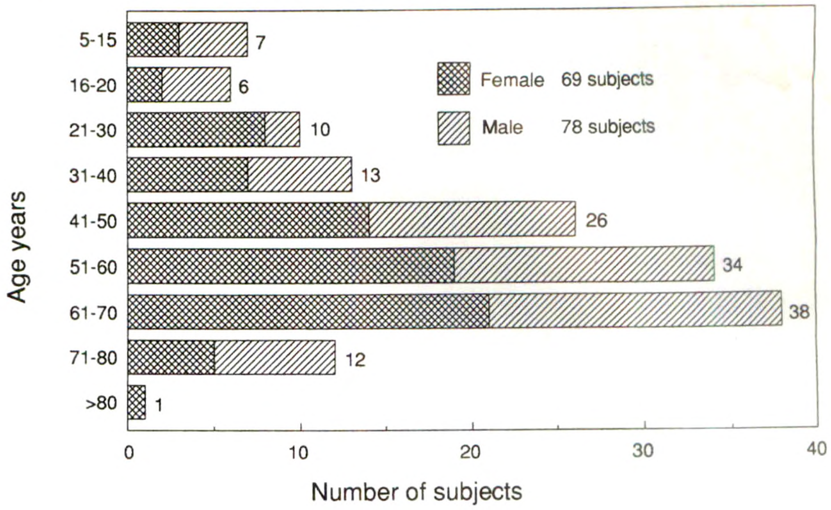


Fig 2. Distribution of age and sex among 147 treated subjects.

DIAGNOSES AND PREVIOUS HEARING AIDS

The subjects of this study had either conductive or mixed hearing losses with the following diagnoses: chronic suppurative or adhesive otitis media and/or external otitis in 107 cases, external ear canal and/or ossicular malformation in 24 cases, and ossicular otosclerosis in 9 cases, as presented in Table 1. Seven subjects, of whom six were severely deaf (BC pure tone average [PTA] >75 dB hearing level [HL]), had sensorineural hearing loss as the only diagnosis. All these subjects were prescribed the HC-200 because they were not satisfactorily helped by conventional hearing aids.

The distribution of types of previous hearing aids ("old aids") is shown in Table 2. Bone conduction aids were, by far, the most common hearing aid in this group of patients. Five subjects had never used a hearing aid long-term before.

AUDIOLOGIC DIAGNOSTIC TESTS

Among the implanted ears, a wide range of conductive and mixed hearing losses are represented, and some subjects had profound sensorineural hearing losses in both ears. Since one of the aims was to define the maximum level of sensorineural hearing loss for patients who benefit from the HC-200, the results were analyzed with reference to the degree of sensorineural hearing loss. As basic preoperative diagnostic tests (headphone TDH39, MX41/AR, and bone conductor Radioear B71), pure tone and speech audiometry were used. The PTAs for the frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz were calculated for BC and AC threshold measurements. Figure 3 shows the distribution of the PTA bone thresholds, the PTA air thresholds, and the air-bone gaps of the 147 implanted ears. For those who have bilateral implants, only data for the ear with the best BC thresholds are presented. One hundred fifteen of the implanted ears had bone thresholds better than or equal to 45 dB HL, whereas only 23 of the implanted ears had bone thresholds in the range from 46 to 60 dB HL. The air-bone gap was, on the average, 35 dB (SD, 15 dB; maximum, 73 dB; minimum, 0 dB).

Pure tone thresholds from the nonimplanted (contralateral) side are not presented here since we assume, for two reasons, that the cochlea on the contralateral side generally has a very small, probably negligible role in hearing by BC with the HC-200. The first reason is that the contralateral cochlea generally has a poorer sensorineural function in the present subjects, since the side with the best cochlear reserve is usually chosen as the implant side; and the second reason is that the mean transcranial attenuation (difference in vibration levels between the mastoid bones), for frequencies from 500 Hz to 10 kHz and among six subjects, is as much as 14 dB.[11] In a recent study, Brandt[11] pointed out that in various narrow frequency bands, antiresonances may cause cancellation of the sound to the ipsilateral cochlea and, hence, the BC sound is lateralized to the contralateral cochlea. Since these frequency bands have relatively small bandwidths, this phenomenon probably plays a minor role in speech intelligibility.

TABLE 1. DIAGNOSES OF 147 TREATED SUBJECTS

	Subjects	
*Diagnoses**	*No.*	*%*
Chronic otitis media	107	73
Malformation	24	16
Otosclerosis	9	6
Profound sensorineural hearing loss	7	5

*For a more detailed description, see text.

TABLE 2. DISTRIBUTION OF TYPES OF OLD HEARING AIDS USED BEFORE HC-200 AMONG 147 TREATED PATIENTS

	Subjects	
Types of Old Hearing Aids	*No.*	*%*
Air conduction	49	34
Bone conduction	80	54
Air and bone conduction	13	9
No hearing aid	5	3

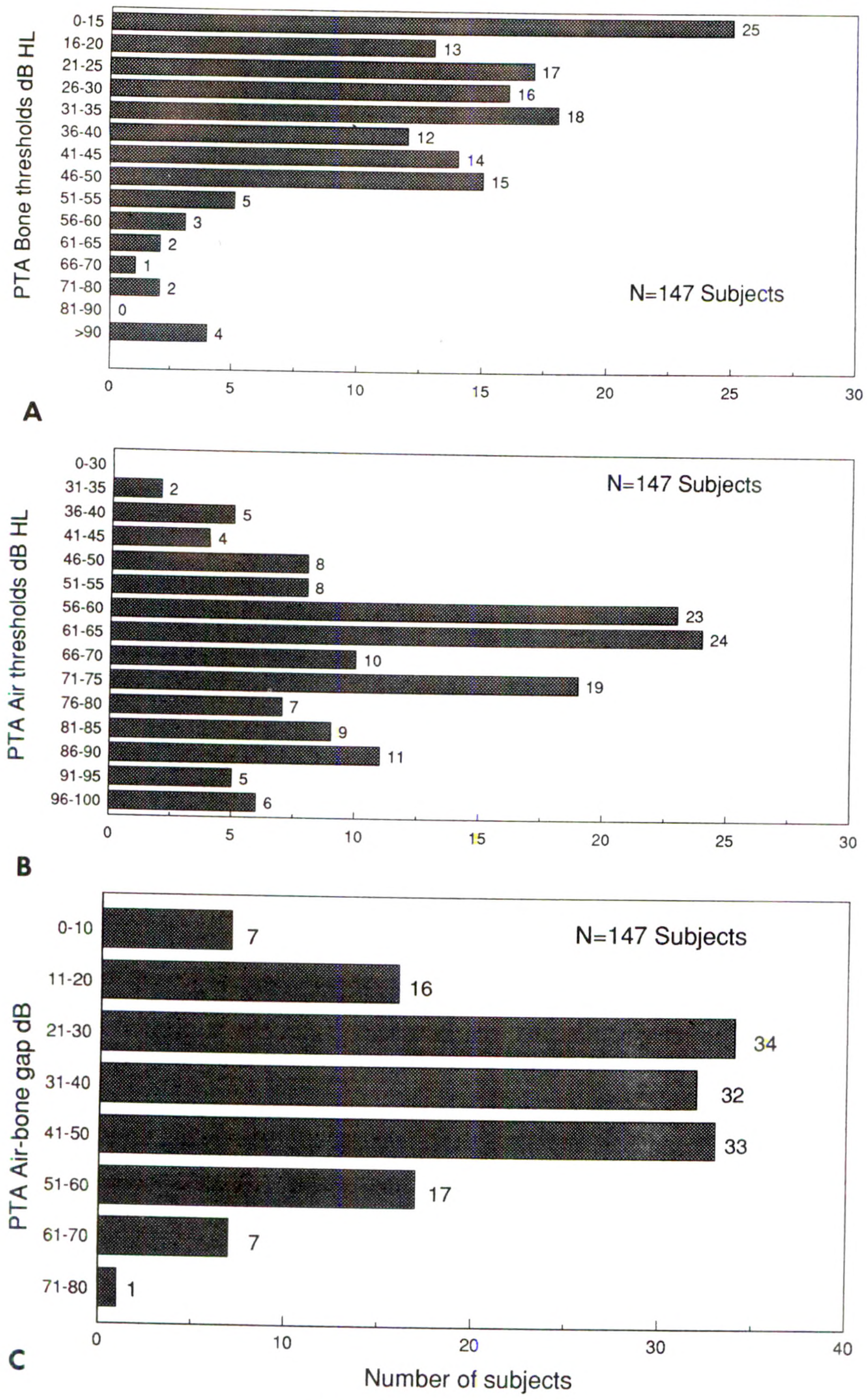


Fig 3. Implanted ears (N = 147). A) Pure tone average bone thresholds in decibels hearing level. B) Pure tone average air thresholds in decibels hearing level. Six subjects did not reach their air thresholds at one or more of the four test frequencies. C) Pure tone average air-bone gap in decibels.

PROCEDURE

SURGERY

The surgical procedures used and their rationale have been described in detail by Tjellström.[12] Briefly, the operation is generally performed under local anesthesia and consists of two stages. During the first stage a cylindrical and threaded hole is made in the mastoid bone, which is then fitted with the titanium bone implant. The soft tissue is closed and the implant remains thereafter mechanically unloaded during a healing period of 3 to 4 months. The second surgical stage is then performed. The subcutaneous tissue around the abutment is reduced and hair-bearing skin is replaced by a graft free from hair follicles. The soft tissue reduction performed during the second-stage operation was carried out in order to prevent irritative interaction between the abutment and the skin. Immobilization of the soft tissues around the abutment is a prerequisite for

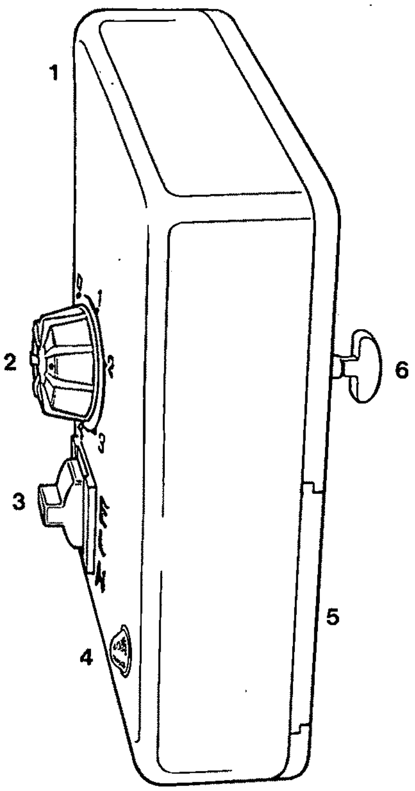


Fig 4. Sound processor HC-200. 1) — housing, 2) — volume control, 3) — tone selector, 4) — microphone, 5) — battery compartment, 6) — transducer piston, E — external, L — low, N — normal.

achieving a reaction-free penetration. The skin-penetrating titanium abutment is then attached to the implant with the connective screw. The sound processor is connected in another 2 to 3 weeks, after primary healing of the skin graft has taken place. Both the first and the second surgical stages are reversible, ie, if for any reason the implant has to be removed, it can be removed without complications.

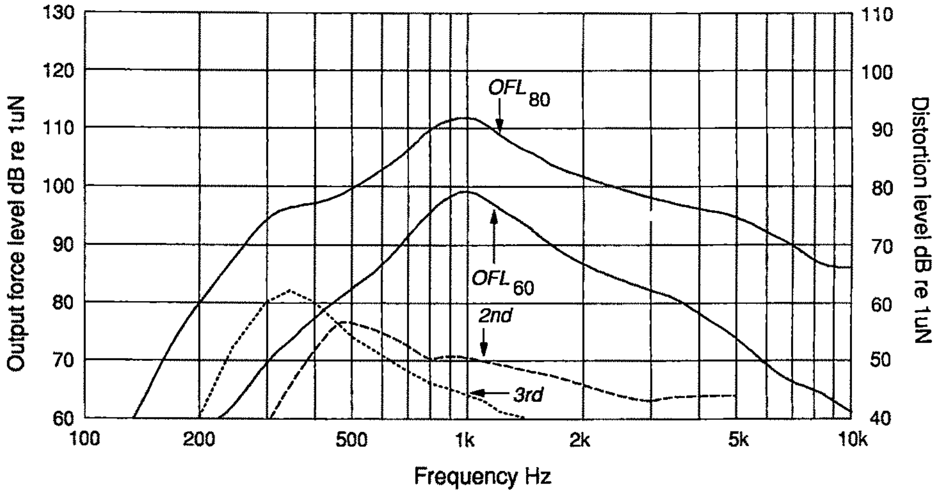
SOUND PROCESSOR HC-200

During the 10 years of clinical trials, the external sound processor has been subjected to modifications, particularly to reduce production costs, to improve reliability, and to facilitate service. On the other hand, the electroacoustic performance as experienced by the patients has not been dramatically changed.

Up to 1986, the sound processor was called the HC-100 and that year the present HC-200 sound processor was introduced. Whereas the HC-100 was basically handmade and produced in prototype series, the design of the HC-200 was changed to adapt to modern techniques for mass production. The major electroacoustic difference between the HC-100 and the HC-200 is that the transducer resonance at about 1 kHz has been smoothed; this change considerably reduces the tendency for the processor to fall into feedback oscillations.[13] Most of the patients in the present study used the HC-100. Since there is a basic similarity between the two models, only the current commercially available design of the HC-200 will be presented in what follows, and the notation HC-200 is used interchangeably with the HC-100.

The sound processor HC-200, depicted in Fig 4, has a three-position tone selector: normal, low, and external. In position N, the subject can select one of four different frequency response characteristics: wideband, bass, treble, and middle-range. Position L gives increased high-frequency attenuation and is intended to be used for a softer sound in noisy environments. In position E, the internal microphone is disconnected. This position is used for listening via a magnetic induction loop system, without hearing the surrounding acoustic sound. The telecoil is encapsulated in a contralaterally worn BiCros device, HC-210, which also includes an additional microphone for binaural listening. The frequency response curves produced by the HC-200, presented in Fig 5, show the output force level relative to 1 μN at input sound pressure levels (SPLs) of 60 and 80 dB. The output force levels are measured with the skull simulator TU-1000.[14] Reference force thresh-

Fig 5. Frequency responses of sound processor HC-200, wideband type, in normal tone switch position and with maximum volume control setting. Output force levels (OFL) were measured at 60 and 80 dB sound pressure level (SPL). Second and third harmonic distortions were measured at 60 dB SPL.



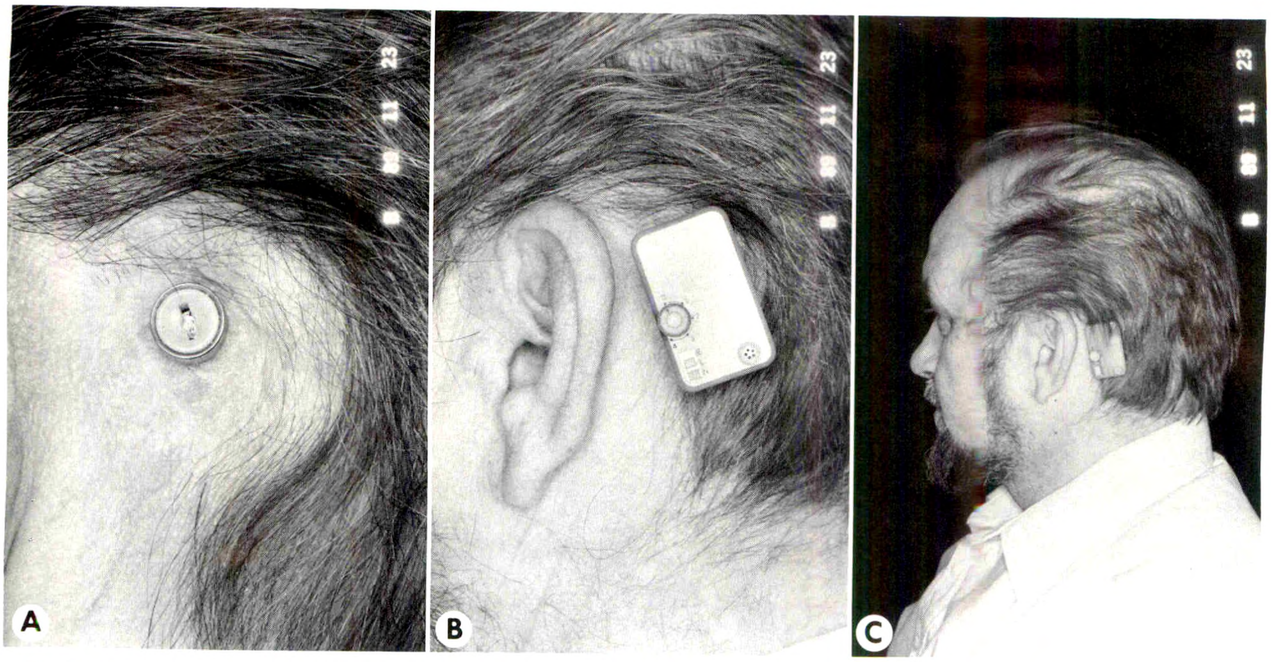


Fig 6. Patient using Swedish bone-anchored hearing system. A) Percutaneous coupling. B) Close-up of sound processor HC-200. C) Patient with sound processor HC-200 as it is normally worn.

olds for hearing by direct BC are discussed in another paper.[15]

FITTING OF SOUND PROCESSOR HC-200

No specific fitting procedure was developed for the HC-100. When model HC-200 was introduced, a more systematic fitting procedure was developed that will now be briefly described.

The sound processor HC-200 is fitted in three consecutive visits to an audiologist during a total period of 5 to 6 months. At the first visit, one of the four different frequency characteristics mentioned above is chosen by means of the master hearing aid HC-250. Once the particular sound processor is chosen, the patient is instructed and trained in how to handle the device. If the patient experiences the sound processor HC-200 as too weak, the more powerful Superbass HC-220 can be used. The audiometer transducer HC-240 is used to measure the force threshold levels directly on the patient, through the bone implant. This is the most relevant method to document the patient's hearing ability with the bone implant and, also, to be able over time to detect changes in his or her hearing ability with the bone implant.

At the second follow-up visit 2 to 3 weeks later, the function of the HC-200 is checked, either by interviewing the patient or by measuring the frequency response with the skull simulator TU-1000. The patient's satisfaction is determined by asking some specific questions. Furthermore, a test is conducted with the HC-250 to check that the frequency characteristic chosen at the first visit is still optimal. There is also a test to see if the patient needs bidirectional microphones and/or a telecoil, which are available as the BiCros HC-210 accessory. The same procedure is normally used at the third follow-up visit.

Figure 6 shows a patient using the Swedish bone-anchored hearing system. From Fig 6C, it is obvious that the sound processor HC-200 is almost invisible in patients with ordinary hairstyles.

METHODS

ASSESSMENT OF TISSUE AROUND ABUTMENT

After the second surgical stage, the subjects were studied at 1 month, 3 months, and 6 months, and thereafter every 6 months. All soft tissue reactions around the percutaneous titanium abutments, from now on referred to as skin reactions, were visually examined and evaluated. The following judgments were used to classify the condition of the skin[16]: 0 — no irritation, 1 — slight redness, 2 — red and moist tissue, 3 — granulation tissue, and 4 — infection leading to removal of abutment.

SUBJECTIVE ASSESSMENT OF HEARING AND COMFORT IN ALL SUBJECTS

All subjects reported their subjective assessment of hearing and comfort when using the HC-200 as compared with their old hearing aid. The definitions of hearing and comfort were presented to the patients briefly as follows. The concept of comfort means how pleasant it is, in general terms, to use the device, ie, including both wearing comfort and sound comfort. The concept of hearing means, in general terms, how the patients experience the

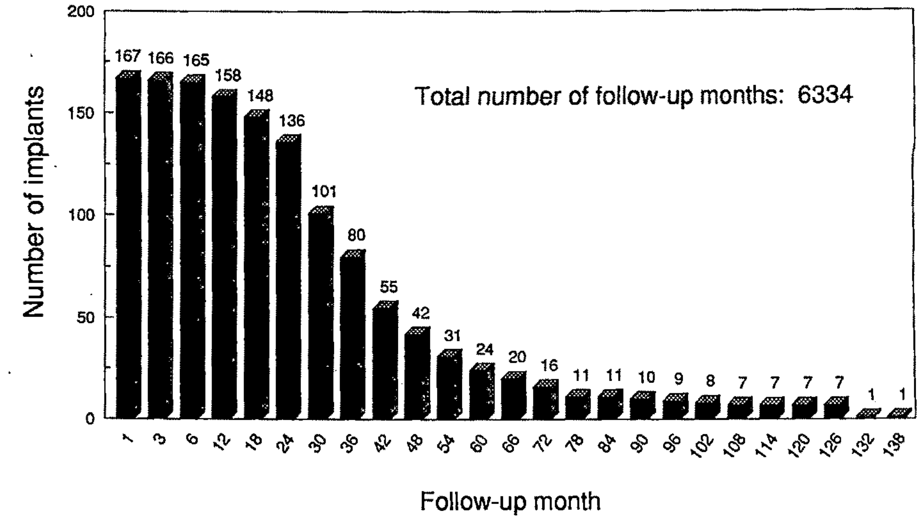


Fig 7. Number of implants versus follow-up month after second-stage surgery.

hearing situation in daily life. The subjects were asked to rank whether the new device was better, worse, or no different as compared with their old devices.

PSYCHOACOUSTIC EVALUATION ON SUBSET OF SUBJECTS

A subset of subjects underwent a more comprehensive audiologic sound field examination. Participation in this extensive study depended mainly on a subject's ability to make the time commitment. Subjects who could come back and forth to Göteborg on the same day were asked to participate. There were 51 persons who volunteered. The following tests were used to compare the subjects' performance using their old conventional hearing aids versus the HC-200.

Sound Field Warble Tone Thresholds. The unaided and the aided sound field warble tone thresholds at frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz were measured. The results of the two aided conditions, "HC-200" and "old aid," were presented relative to the result of the "unaided" condition, thus giving the functional gain for free field tone thresholds. In all aided conditions, the volume control was adjusted to the most comfortable loudness (MCL). These measurements were performed in a soundproof room with the subject facing the loudspeaker at a distance of 1 m. The sound field warble tones were calibrated according to ISO 226 (1987),[17] with a 2-dB adjustment for monaural listening. The results were checked on 10 normal-hearing subjects by use of the conventional technique for threshold measurements. To make examination possible for subjects with large asymmetric hearing losses (BC PTA>20 dB), masking was used with an insert earphone in the nontest ear.

Sound Field Discrimination of Monosyllabic Swedish Words in Quiet. Discrimination of monosyllabic words (Swedish phonetically balanced word lists) at a normal conversational level of 63 dB SPL in a sound field without background noise was measured with the old aid, with the HC-200, and unaided.

Synthetic Sentence Identification Test in Speech Noise. A Synthetic Sentence Identification test in "speech noise" was performed with both the old aid and the HC-200. The speech was presented at a constant level of 63 dB SPL. The speech noise levels yielding 50% sentence intelligibility with the two devices were determined.[18]

Also, the HC-200 was retested at the same signal-to-noise ratio as that obtained with the old aid, to see if and how much the discrimination score increased or decreased from 50%.

Questionnaire on Performance of HC-200. Utilization time per day and the frequency of battery replacement with the new HC-200 device was registered by the subjects.

The subjects had to compare aspects such as sound quality, wearing comfort, status of ear infections, esthetic appearance, and ease of handling. Particularly, the subjects were asked to assess the performance of the HC-200 under various listening conditions.

RESULTS

ASSESSMENT OF TISSUE AROUND ABUTMENT

The follow-up time varied from 1 month to 11.5 years and comprised an accumulated number of

TABLE 3. DISTRIBUTION OF TYPES OF SKIN REACTIONS AMONG 167 IMPLANTS

	Observations	
Types of Skin Reactions	*No.*	*%*
0: no irritation	1,152	93.2
1: slight redness	51	4.1
2: red and moist tissue	16	1.3
3: granulation tissue	16	1.3
4: infection leading to removal of abutment	1	0.1
Total	1,236	100.0

TABLE 4. DISTRIBUTION IN PERCENT OF TYPES OF SKIN REACTIONS WITH REFERENCE TO FOLLOW-UP MONTH AMONG 167 IMPLANTED EARS

		Types of Skin Reactions					
Follow-up Month	*No. of Observations*	*0*	*1*	*2*	*3*	*4*	*Average Score*
1	166	98.8	1.2	0.0	0.0	0.0	0.01
3	156	95.5	4.5	0.0	0.0	0.0	0.04
6	140	87.9	7.1	1.4	3.6	0.0	0.21
12	143	92.3	5.6	0.0	1.4	0.7	0.13
18	125	92.0	4.0	2.4	1.6	0.0	0.14
24	122	93.4	1.6	2.5	2.5	0.0	0.14
30	84	94.0	2.4	3.6	0.0	0.0	0.10
36	69	91.4	5.8	1.4	1.4	0.0	0.13
42	47	87.2	8.5	0.0	4.3	0.0	0.21
48	36	97.2	2.8	0.0	0.0	0.0	0.03
54	25	96.0	0.0	4.0	0.0	0.0	0.08
60	21	95.2	0.0	4.8	0.0	0.0	0.10
66	17	82.4	11.8	0.0	5.8	0.0	0.29
72	14	92.9	7.1	0.0	0.0	0.0	0.07
78	11	100.0	0.0	0.0	0.0	0.0	0.00
84	10	90.0	0.0	10.0	0.0	0.0	0.20
90	7	85.7	0.0	14.3	0.0	0.0	0.29
96	7	85.7	14.3	0.0	0.0	0.0	0.14
102	8	87.5	12.5	0.0	0.0	0.0	0.13
108	6	83.3	16.7	0.0	0.0	0.0	0.17
114	7	100.0	0.0	0.0	0.0	0.0	0.00
120	6	100.0	0.0	0.0	0.0	0.0	0.00
126	7	100.0	0.0	0.0	0.0	0.0	0.00
132	1	100.0	0.0	0.0	0.0	0.0	0.00
138	1	100.0	0.0	0.0	0.0	0.0	0.00
Total*	1,236	93.2	4.1	1.3	1.3	0.1	0.10
Long-term average†	434	92.5	4.9	0.8	1.8	0.0	0.14
Worst case§	167	70.7	14.3	7.2	7.2	0.6	0.53

Types of skin reactions are defined in Table 3.

"Average score" is for all observations at each follow-up month.

*Results based on all 1,236 observations.

†Results based on implants with clinical follow-up longer than 42 months comprising 42 implants and 434 observations.

§Results based on worst (highest) classification score recorded for each of 167 implants.

6,334 months (Fig 7). The implants have been observed from 1 to 25 times, or from 1 month to 138 months. A total of 1,236 observations have been made, and Table 3 presents the distribution of the different types of skin reactions. Ninety-three percent of the observations were judged as normal, ie, having no sign of adverse skin reaction.

Skin reaction type 1, which is mild in nature and is normally not observed by the subject himself or herself, was registered in 4.1% of the observations. These subjects were told to exercise careful hygiene and use an antibiotic ointment. Skin reactions that required repeated outpatient care (groups 2, 3, and 4) were only 2.7% of the total number of observations. Type 2 reactions were found 16 times, all in different subjects. The skin penetration area was carefully cleaned and treated with antibiotic ointment for these subjects. Type 3 reactions were found 16 times in 13 subjects. The treatment of these subjects varied; in some, the granulation tissue was removed and an ointment-impregnated gauze strip was wound around the abutment for a few days. In others, a free skin graft was used to replace the damaged tissue. The one subject with a type 4 reaction, in which the abutment had to be removed because of skin infection, was a patient with seborrhea and poor personal hygiene. When the coupling was removed, the bone implant and some of the adjacent bone tissue were removed with a trephine bur at the same time and examined histologically. In spite of the infection that had lasted for a couple of months, there was no sign of osteitis or other adverse reactions in the bone. The healing was uneventful. This unique case has been reported in a separate study.[19]

In Table 4 the distribution of types of skin reactions is given for each of the follow-up occasions, and no apparent increased complication rate over time could be observed. The average score, ie, sum of skin reaction classification numbers divided by number of implants for each follow-up month, ranged from 0.01 to 0.21 during the first 60 months. No clear tendency of increasing average scores could be observed. Moreover, if implants with clinical follow-up periods longer than 42 months are considered (42 implants and 434 observations), the results achieved were almost identical with the average results of all observations (±0.8%). This fact further strengthens the argument that there are no time-related factors involved in the material pre-

TABLE 5. NUMBER OF REMOVED OR CHANGED ABUTMENTS AND SOFT TISSUE REDUCTIONS IN 167 IMPLANTED EARS

Causes	*Abutments Removed*	*Abutments Changed*	*Tissue Reduction*
Skin infection	1		
Discomfort, psychological reasons	5		
No hearing improvement	7		
Trauma	2		
Bone implant not integrated	1		
Inadequately hygienic and loose coupling		9	
Thick and movable skin			10
Total	16	9	10

sented here. In evaluating the worst classification score for each patient, it was found that in 85% of the implants "slight redness" was the worst condition ever observed.

A total of 16 abutments were removed for various reasons, as reported in Table 5. In 5 subjects, the abutments were removed because of unexplained discomfort or for psychological-cosmetic reasons. Seven subjects with profound sensorineural hearing loss as the only diagnosis did not experience satisfactory hearing improvement and the abutments were removed. These 12 subjects were all from the beginning of the study, before the selection criteria were established. A bone implant was not always removed when an abutment was taken off. However, in some subjects the bone implant was removed, together with the surrounding bone for histology, or unscrewed in order to measure the removal torque. Data from these measurements have been gathered by Yamanaka et al.[20]

During the study, nine abutments were changed, as the initial design of the coupling was improved. Abutment replacements were done early in the study, before the final design and tolerances of the couplings had been established. In 10 subjects, also from the first group of patients fitted with the new device, the subcutaneous tissue reduction had not been made extensive enough and a revision operation was performed to avoid future skin reactions.

SUBJECTIVE ASSESSMENT OF HEARING AND COMFORT IN ALL SUBJECTS

All 146 subjects expressed their opinions about the HC-200 with respect to hearing and comfort in comparison with their old aid. The bone implant of 1 subject of the original 147 did not integrate properly into the bone and this subject was excluded.

The subjects were divided into three groups according to their cochlear function, ie, the PTA bone thresholds. In the first group, the results of all 113 subjects with bone thresholds equal to or better than 45 dB HL were included. The second group comprised 23 subjects with bone thresholds between 46 and 60 dB HL. In the third group, results were reported for the remaining 9 subjects with PTA bone thresholds worse than 60 dB HL. In Table 6 the opinions of all 146 patients are summarized, group by group, whereas in Table 7 the results are presented globally with respect to increasing bone threshold.

TABLE 6. SUBJECTIVE ASSESSMENT OF HEARING AND COMFORT IN RELATION TO PURE TONE AVERAGE BONE THRESHOLDS IN 146 SUBJECTS USING HC-200

Bone Conduction Pure Tone Average (dB hearing level)	*Improved*	*Worse*	*No Difference*	*p**
Hearing				
0-45	102(89%)	8	4	<.001
46-60	14(61%)	6	3	.2
61-	2(22%)	4	3	>.5
Comfort				
0-45	108(95%)	4	2	<.001
46-60	19(83%)	1	3	.001
61-	2(22%)	2	5	>.5

*Sign test in which number of "improved" was compared with numbers of "worse" and "no difference."

It is obvious from both Table 6 and Table 7 that there is a strong relation between PTA bone thresholds and successful rehabilitation. The percentage of subjects who reported both improved hearing and improved comfort increased from 81% to 89% and from 88% to 95%, respectively, when the maximum allowable PTA bone thresholds decreased from 60 to 45 dB, as reported in Table 7. In the same manner, the percentage of subjects who reported worse hearing and comfort decreased from 12% to 7% and from 5% to 3%, respectively, with decreased PTA bone thresholds.

PSYCHOACOUSTIC RESULTS FOR SUBSET OF PATIENTS

Sound Field Warble Tone Thresholds. As shown by the average functional gain (aided thresholds relative to unaided sound field thresholds) obtained with HC-200 and old hearing devices presented in Fig 8, there is a surprising resemblance between the old and the new situations. This result can be ex-

TABLE 7. RESULTS OF SUBJECTS' SUBJECTIVE ASSESSMENT OF HEARING AND COMFORT IN RELATION TO MAXIMUM PURE TONE AVERAGE BONE THRESHOLD ALLOWED

Bone Conduction Pure Tone Average (dB hearing level)	*No. of Subjects*	*Improved*	*Worse*	*No Difference*
Hearing				
No limit	146	81%	12%	7%
≤60	137	85%	10%	5%
≤45	114	89%	7%	4%
Comfort				
No limit	146	88%	5%	7%
≤60	137	93%	3.5%	3.5%
≤45	114	95%	3%	2%

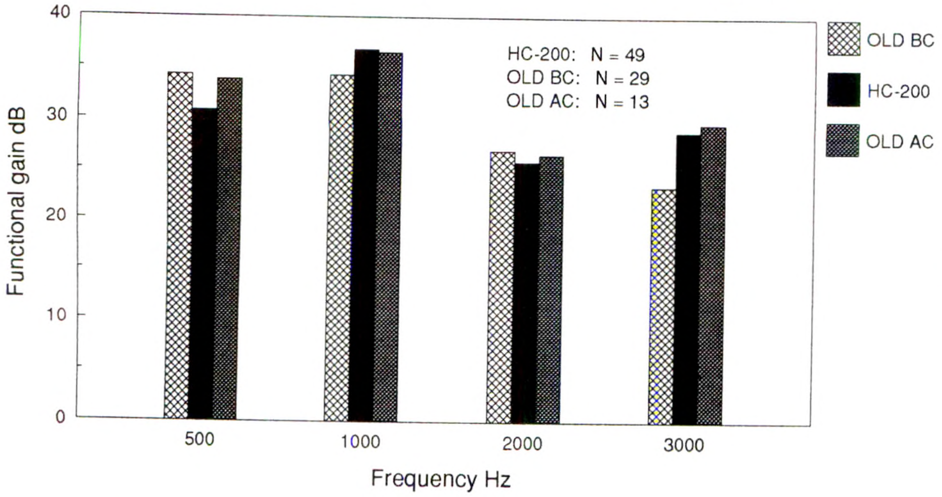


Fig 8. Average functional gain for free-field warble tone thresholds with HC-200 and old hearing aids. Volume control was adjusted to most comfortable loudness. BC — bone conduction hearing aid, AC — air conduction hearing aid.

plained by the fact that the subjects, when told to adjust the volume control to MCL for speech, adjusted the volume control for equal loudness, yielding approximately the same sensitivity for "threshold level" sounds. On the other hand, the difference between the unaided and both aided conditions was found to be statistically significant ($p<.001$), and all subjects showed an improvement at each frequency. One apparent discrepancy in Fig 8 is that the old BC hearing aid has a lower sensitivity at high frequencies, as has also been pointed out by Håkansson et al.[8] The functional gain is highly individual, as is illustrated by Fig 9, in which the functional gain for the HC-200 is presented in greater detail. These data are based on 49 subjects and incorporate, besides mean and SD, also the range (maximum and minimum) among all these subjects. The great spread in functional gain probably reflects a great spread in conductive hearing loss. This influence from conductive hearing loss on functional gain can probably be explained by the fact that aided BC thresholds are mostly independent of the conductive hearing loss, whereas the unaided thresholds are not.

The maximum functional gain with a particular BC hearing aid is obtained if the unaided and the aided sound field thresholds are measured on a subject who has a maximum conductive hearing loss (approximately 60 dB) and if the volume control setting is adjusted to maximum (not MCL). This maximum functional gain has not been measured in the present study, but it can be assumed that the maximum values in Fig 9 are very close to the maximum functional gain with the HC-200, since in this study some subjects had almost a maximum conductive hearing loss and at the same time had poor sensorineural hearing (ie, had the volume control at maximum).

Sound Field Discrimination of Monosyllabic Swedish Words in Quiet. Table 8 shows the results from 47 subjects who underwent the sound field speech discrimination test. As shown, the subjects demonstrated an average discrimination score of 14%

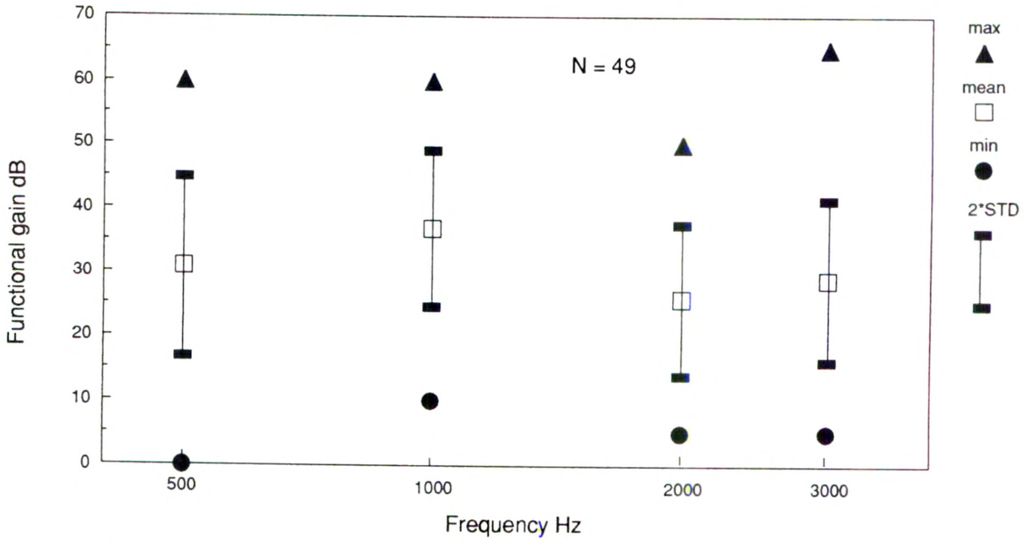


Fig 9. Mean, SD, and maximum and minimum values of free-field functional gain for 49 subjects using HC-200.

TABLE 8. RESULTS OF SOUND FIELD SPEECH DISCRIMINATION TESTS IN QUIET

Device	*No. of Subjects*	*Mean (%)*	*SD (%)*
Unaided	47	14	23
HC-200	47	81	21
Old BC	24	80	23
Old AC	23	67	28

BC — bone conduction hearing aid, AC — air conduction hearing aid.

under unaided conditions with the phonetically balanced words at a speech level of 63 dB SPL. Among the aided conditions, the HC-200 performed the best with 81% as an average for the whole group. This improvement from the unaided to the HC-200 condition is statistically significant ($p < .001$). Those who used old BC aids performed almost as well as those who used the HC-200 (80%), whereas patients with old AC hearing aids performed considerably worse (67%). No statistically significant difference between the different aided conditions was detected.

Synthetic Sentence Identification Test in Noise. Twenty subjects had used AC hearing aids and 25 had used BC hearing aids previous to implantation. A comparison of signal-to-noise ratios was made to compare the performance of the HC-200 and the subject's old aid.

As presented in Table 9, subjects using the HC-200 generally tolerated higher noise levels as compared with their old BC aids (−2 dB) and their old AC aids (−0.8 dB). Note that a minus sign in this comparison means that the HC-200 allowed the subject to tolerate a higher noise level, still having 50% intelligibility, compared with the old device, when the sound level is constant.

It is interesting to translate this higher noise endurance with the HC-200 to a change in discrimination score at a constant signal-to-noise ratio by actually measuring the intelligibility with the HC-200 at the same signal-to-noise ratio as that obtained with the old aid. The results presented in Fig 10 show that the discrimination score for the BC group improved from 50% to 71% and for the AC group from 50% to 60%. These differences were statistically significant ($p < .001$).

TABLE 9. COMPARISON BETWEEN SIGNAL-TO-NOISE RATIOS GIVING 50% INTELLIGIBILITY AMONG 45 SUBJECTS

Conditions	*No. of Subjects*	*Mean (dB)*	*SD (dB)*	*p**
HC-200 vs old BC	25	−2.0	2.6	.02
HC-200 vs old AC	20	−0.8	2.7	.13

BC — bone conduction hearing aid, AC — air conduction hearing aid.

*Sign test in which number of "improved" (HC-200 vs old <0) was compared with numbers of "worse" or "no difference" (HC-200 vs old ≥0).

Questionnaire on Performance of HC-200. The subjects' opinions, investigated by means of a questionnaire, are usually the most important and reliable measures for assessing the rehabilitation benefits provided by a new hearing device.

More than 90% of the subjects reported that they used their HC-200 more than 8 hours every day. No patient reported not using the HC-200 at all. A change of batteries was required once a week for 42%, every 2 weeks for 38%, and every 3 weeks or more for 20% of the subjects.

In Table 10, the results from questions used to evaluate the subjects' views on the relative merits of the HC-200 as compared with their old aids are summarized. The ear infections were significantly reduced if the subject had previously used an earmold (AC hearing aid). In those subjects who had previously used BC aids, the middle ear condition was not significantly affected. Moreover, the general opinion was that the HC-200 offered a better

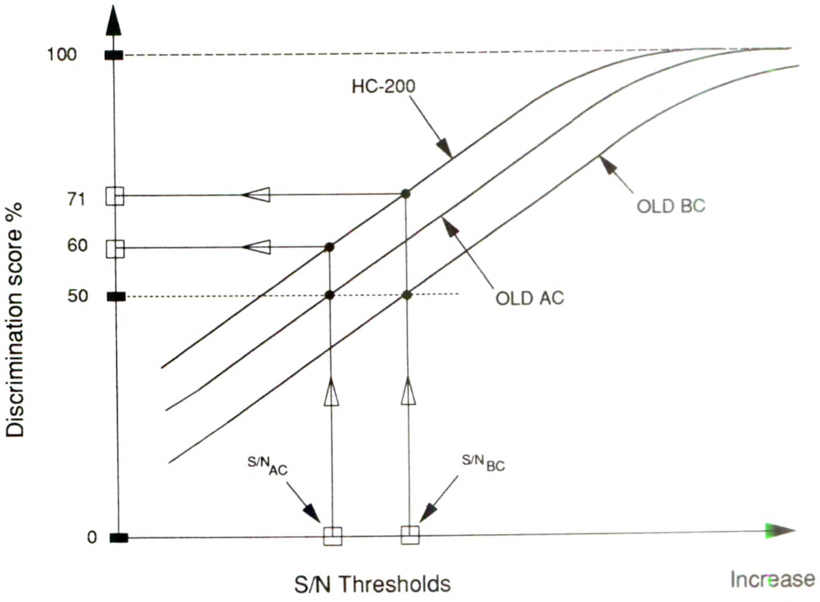


Fig 10. Average discrimination score obtained with HC-200 tested at signal-to-noise (S/N) ratios giving 50% discrimination with old hearing aids. AC — air conduction hearing aid, BC — bone conduction hearing aid.

TABLE 10. SUBJECTS' ASSESSMENTS OF HC-200 AS COMPARED WITH OLD AID

	Old Aid	*No. of Subjects*	*Improved*	*Worse*	*No Difference*	*p**
Ear infection	AC	24	22	0	2	<.001
	BC	27	12	4	11	>.5
Sound quality	AC	24	16	3	5	.08
	BC	27	20	3	4	.01
Esthetic appearance	AC	24	13	5	6	.42
	BC	27	20	4	3	.01
Practical handling	AC	24	13	5	6	.42
	BC	27	21	0	6	.003
Wearing comfort	AC	24	10	5	9	>.5
	BC	27	19	4	4	.026

AC — air conduction hearing aid, BC — bone conduction hearing aid.

*Sign test in which number of "improved" was compared with numbers of "worse" and "no difference."

quality of sound, was easier to use, was more cosmetically attractive, and was more comfortable to wear in comparison with the old aids.

The positive psychoacoustic test results concerning the quality of sound with the HC-200 versus the old aids were confirmed by the subjects' own opinions, which are presented in Table 11.

Almost all of the patients also stated that their quality of life had improved considerably since they started to use the HC-200. A scale from 1 to 10 divided in equal parts was used to assess the patients' opinions about the HC-200; 1 stands for dissatisfaction and 10 for high satisfaction. The average opinion was found to be slightly above 9.

DISCUSSION

ASSESSMENT OF TISSUE AROUND ABUTMENT

The most important property for an implant permanently penetrating the skin is, of course, that the device should cause no or a minimum of adverse reactions. The prerequisite for this is the stability of the arrangement, ie, the skin close to the penetration point must not move in relation to the implant. Hence, a stable anchorage in the bone is essential. Only 1 of the 167 bone implants placed in the mastoid process was found not to be integrated. This was in a young patient with a congenital malformation and with a rare bone disease that it has not been possible to classify. The bone implant was noted to be loose within 6 months after insertion. The cortical bone of the mastoid in this child was very thin, but it should be noted that among the other 166 patients there are several with only a 1.5-mm-thick cortex in whom the bone implants are stable.

There are two main questions raised in the evaluation of the soft tissue investigation: 1) What is the overall rate of adverse skin reactions? and 2) Does the rate of adverse skin reactions increase with time? To answer question 1, we need to know the answer to question 2, since one can never give a rate of the skin reactions without including an assumption regarding time-dependence. We have therefore presented our skin reaction data as the average of all observations of all implants over a defined period of time (see Table 3).

Table 4 is an attempt to show, as clearly as possible, that we could not find any increased rate of adverse skin reactions over time (see Average Score and Long-term average).

Assuming that the average result as presented in Table 3 is time-invariant, one can interpret it as follows: every time a patient comes for a 6-month follow-up, no matter if it is after 12 months or 132 months, he or she has a 93% chance of being classified as 0, a 4% chance to be classified as 1, etc.

Another way to interpret these figures is the following. During, for example, the next 4 years a patient will come back for follow-up every 6 months (eight times). At each follow-up he or she will still have a 93% chance of being classified as 0, but the chance of having 0 at all eight consecutive follow-ups is, of course, considerably reduced. This effect is also shown in Table 4 by the percentages for "Worst case," which are considerably lower than

TABLE 11. SUBJECTS' ASSESSMENTS OF HC-200 IN VARIOUS LISTENING SITUATIONS

	Old Aid	*No. of Subjects*	*Excellent*	*Very Good*	*Moderate*	*Poor or Useless*	*p**
Talking to one person	AC	24	11	10	3	0	<.001
	BC	27	17	10	0	0	<.001
Listening to music	AC	24	8	11	5	0	.003
	BC	27	13	7	3	4	.01
Group conversation in background noise	AC	15	1	3	10	1	>.5
	BC	20	6	7	7	0	.13

AC — air conduction hearing aid, BC — bone conduction hearing aid.

*Sign test in which numbers of "excellent" and "very good" were compared with numbers of "moderate" and "poor or useless."

the overall average scores. As a consequence, the worst-case data have to be connected to a period of time, preferably the average follow-up time. The average follow-up time per implant in the present study is approximately 38 months, which corresponds to eight visits (three visits during the first 6 months).

On the basis of the present results, it can be stated that the use of titanium bone implants in the temporal bone and the creation of a permanent skin penetration entails a very low risk for complications. In every medical or surgical treatment modality, there are risks that have to be considered in relation to the benefit.

On the basis of the extremely good psychoacoustic as well as psychological results, the risk factor of a permanent skin penetration seems clearly to be offset by the benefits. The same conclusion is also drawn by Abramson et al[21] and by Bonding et al,[22] who independent of the Göteborg group (present study) have operated on, fitted, and evaluated a number of subjects in the United States and Denmark, respectively, with the Swedish bone-anchored hearing system.

SUBJECTIVE AND PSYCHOACOUSTIC EVALUATIONS

Differences in sound quality between different types of hearing aids are difficult to evaluate with psychoacoustic tests.[23,24] This difficulty has primarily to do with the relatively low reliability of speech discrimination tests.[25] Pascoe[26] also points out the limitations of comparative and prescription hearing aid evaluation methods. Sound field testing with warble tones and speech discrimination tests in quiet and noisy surroundings have to be supplemented by the subject's own judgment about the quality of the hearing device. All 146 subjects reported their subjective opinions, and sound field measurements were performed on 51 of the subjects.

With the Synthetic Sentence Identification test in speech noise it was demonstrated that those who had used BC aids before using the HC-200 could tolerate a 2-dB-higher noise level and maintain an unchanged intelligibility of 50%. This finding is in accordance with the results of Carlsson et al,[27] who found an average improvement of 3.3 dB in 28 subjects.

MAXIMUM LEVEL OF SENSORINEURAL HEARING LOSS

It was of special interest to analyze the subjects' experience of hearing and wearing comfort improvements in relation to their preoperative PTA bone thresholds. As shown in Table 7, 81% of all subjects experienced improved hearing with the present HC-200. This figure increased to 85% if the persons with sensorineural hearing losses below 60 dB HL were excluded, and to 89% if subjects with PTA bone thresholds worse than 45 dB HL were excluded. The comfort was increased in the same groups from 88% to 93% and 95%, respectively. On the basis of the present material, bone PTA thresholds equal to or better than 45 dB HL indicate that the HC-200 as a rule will provide significant hearing improvement. We therefore recommend consideration of this level as a borderline for a "high" success rate. When the PTA bone thresholds are worse than 45 dB HL, the hearing improvement depends on the cochlear reserve. In our material, approximately 61% of those with PTA bone thresholds between 46 and 60 dB HL considered themselves as having improved their hearing, and 83% considered themselves as having improved comfort. For most subjects in this group, especially those who have reported "worse" or "no difference" situations, the more powerful model HC-220 can most likely be beneficial. Our preliminary results indicate that the limit of 45 dB HL for the HC-200 has been increased to approximately 60 dB HL for an "equally" high success rate with the HC-220 (unpublished observations).

INDICATIONS AND PRESCRIPTION RULES FOR HC-200

Principal indications for the HC-200 are as follows: 1) chronic otitis media, at times accompanied by external otitis, 2) congenital malformation of the middle and/or external ear, and 3) otosclerosis or tympanosclerosis in special cases (see 5, below).

Our indications for implantation of patients are as follows:

1. Any patient who uses a conventional BC hearing instrument.
2. Any patient who uses an AC hearing aid and has a chronically draining ear that has failed good conservative treatment.
3. Any patient needing amplification who experiences pain or discomfort when using a conventional AC hearing aid because of chronic middle and/or external ear disease.
4. Any patient who has had a radical mastoidectomy and meatoplasty with uncontrollable feedback when using an AC aid.
5. Any patient with otosclerosis or tympanosclerosis on one side and profound deafness on the other side. Also, patients with the diagnosis of otosclerosis in combination with the conditions described under points 2 through 4, above, are suitable candidates.

Contraindications. For an optimal result the following limitations should be taken into consideration, even though they should not be considered as absolute contraindications: 1) PTA BC thresholds (0.5 to 3.0 kHz) worse than 45 dB HL (this limit is adjusted to approximately 60 dB HL for the HC-220); 2) emotional instability, developmental delay,

TABLE 12. DISADVANTAGES OF ALTERNATIVE TREATMENTS

	Air Conduction Hearing Aid	*Bone Conduction Hearing Aid*	*Reconstructive Surgery*
Chronic otitis media	Presence of earmold aggravates infection	Pain from static pressure	Difficult procedure
	Pain from ear canal infection	Skin irritation	Repeated procedures often necessary
	Acoustic feedback	Poor sound quality	General anesthesia often needed
		Headband holder is unesthetic	High costs for repeated procedures
		Positional variations	Risk for cochlear and vestibular losses
		High power consumption	
Congenital malformation	Cannot be used	Same as for chronic otitis media	Same as for chronic otitis media
			Risk of facial nerve damage
			Risk of creating draining ear

or drug abuse; and 3) age less than 5 years.

Speech audiometry is a valuable tool in assessing borderline cases. A speech discrimination score of better than 60% is generally required in order to assure a high success rate.

ESTIMATED NEED OF BONE-ANCHORED DEVICES

In the United States there are no statistics available on the use of conventional BC devices. In Sweden all hearing aids are distributed through a semipublic organization that maintains records of the number of different types of hearing aids prescribed. During the period 1978 to 1988, about 75 to 150 BC aids per 1 million inhabitants were distributed annually in Sweden. These include both bone conductors attached to bows of eyeglasses and bone conductors with headbands. The actual need, however, is greater because of the relatively poor function of conventional BC hearing aids. From this study it is evident that this factor induces many patients either to not use an aid at all or to continue using an ordinary AC instrument even if it causes the ear to drain.

ALTERNATIVE TREATMENT AND PROCEDURES

Conventional Treatment by Hearing Aids and Surgery. Conventional BC hearing aids, mounted on steel headbands or on the temple-hugging earpieces of a pair of glasses, and AC hearing aids are, as already mentioned, alternatives to the HC-200. The disadvantages of such alternatives are summarized in Table 12.

Reconstructive surgery is, of course, an alternative. In cases of congenital malformations (atresia), successful results are difficult to obtain, and repeated procedures are often needed. Atresia correction is considered by some as one of the most difficult procedures in reconstructive ear surgery. The disadvantages of reconstructive ear surgery are summarized in Table 12.

Xomed Audiant Bone Conductor. For some patients, an alternative that has recently become available (Food and Drug Administration approval 1987) is the Audiant Bone Conductor, marketed by Xomed, Inc, a Bristol-Myers company. The transducer for the Xomed device consists of two parts, one totally implanted part comprising a rare earth magnet housed in a titanium disk, which is rigidly attached to the skull, and one externally worn part comprising the sound processor (including a second rare earth magnet and an induction coil). There is no percutaneous connection between the implanted part and the externally worn part, and as a consequence, this type of BC is called transcutaneous direct BC. The disadvantages with the Xomed device as compared with the HC-200 are as follows.

1. The fact that the gap in the Xomed transducer is 2 to 6 mm (filled with soft tissue) instead of 0.06 to 0.08 mm (air gap) in the HC-200 device results in considerably less efficient transduction. This lower efficiency manifests itself technically in higher current consumption and lower maximum output, and practically in that the patient must have an almost normal inner ear to benefit from the device (Table 13).

TABLE 13. COMPARISON BETWEEN XOMED DEVICE AND HC-200 DEVICE

Specification	*HC-200*	*Xomed (A.T.E.)*
Current drain (mA)	1	26.7*
Maximum output (dB relative to 1 μN)	111	91
Bone conduction pure tone average (dB hearing level)	≤45†	≤25
Air conduction pure tone average (dB hearing level)	No limit	≥40
Discrimination score (%)	≥60	≥80
Age (y)	≥ 5§	≥3

Pure tone averages are based on four frequencies (0.5, 1, 2, and 3 kHz) for HC-200 and on three frequencies (0.5, 1, and 2 kHz) for Xomed device.

A.T.E. — At-The-Ear.

*Estimated average current drain at 1, 1.6, and 2.5 kHz giving same mechanical output as produced by HC-200 at 1 mA current drain.

†60 dB for Superbass HC-220.

§Recent pilot study on children 3 years of age indicates promising results.

TABLE 14. COST ANALYSIS FOR ALTERNATIVE TREATMENT

Treatment	*Conditions*	*Cost*
Surgery (chronic suppurative otitis media)*	Inpatient basis	$4,900-6,300§
Surgery (atresia)*	Inpatient basis	$5,700-6,200§
Xomed Audiant*	Inpatient basis	$5,900
Xomed Audiant*	Outpatient basis	$4,700
HC-200†	Outpatient basis	$2,500

*According to Gates et al.[29]

†According to Sahlgren Hospital (see text for further explanation).

§Cost depends on extensiveness of procedure.

2. Discomfort from compression and inflammation of the soft tissue between the magnets when using a conventional BC device is a problem for some patients with the Xomed device.

3. The frequency response of the Xomed device is not under adequate control, since the condition and properties of the patients' soft tissues determine the frequency response of the device.

The major differences between the HC-200 and the Xomed devices, with respect to technical performance and audiologic indications, are summarized in Table 13. A more detailed description of the differences between the Xomed device and the HC-200 device is presented by Håkansson et al.[28]

COST ANALYSIS

According to Gates et al,[29] the treatment by the Xomed device is cost-efficient if it reduces the number of surgical procedures from two to one, since the cost for one surgical treatment is approximately the same as the cost of the device (Table 14[29]). The same statement can be made for the HC-200. The costs for the surgeon ($100) and the hospital ($200) are the actual costs without any profit, calculated by the local health authorities in Göteborg, and what is charged for Swedish patients. These costs, of course, will vary from country to country, as they will with the Xomed device.

CONCLUSIONS

The surgical procedures to install titanium bone implants into the skull and to permanently penetrate the soft tissues by a skin-penetrating titanium abutment can be classified as being well established, minor, and almost risk-free. Skin-penetrating abutments cause only a few cases of adverse skin reactions. The surgical procedures are reversible, ie, if the patient for some reason does not want to keep the skin-penetrating coupling, it is easy to remove it without any future complications.

The subjects' positive opinions about the HC-200 were confirmed by results obtained in audiologic tests.

The contributions to improved quality of life by using HC-200 as compared with conventional hearing aids for hearing-impaired patients with chronically draining ears, malformed ears, or otosclerosis or tympanosclerosis can be characterized by a combination of one or more of the following statements: 1) improved quality of sound, 2) improved comfort, 3) better appearance, and 4) diminished risk for ear infections and facilitated healing of ongoing chronic ear infections.

By using the ear-level sound processor HC-200, patients with bone thresholds down to 45 dB PTA can be successfully treated in approximately 90% of the cases. With the Superbass transducer HC-220 (body-level device), patients with bone thresholds down to approximately 60 dB PTA probably have an equally good chance of being successfully rehabilitated.

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IMPACT OF THE ACQUIRED IMMUNODEFICIENCY SYNDROME EPIDEMIC ON THE PRACTICE OF LARYNGOLOGY

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IMPACT OF THE ACQUIRED IMMUNODEFICIENCY SYNDROME EPIDEMIC ON THE PRACTICE OF LARYNGOLOGY

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In only 10 years, the acquired immunodeficiency syndrome epidemic has already had an enormous impact on many aspects of the practice of medicine. The practice of laryngology typifies the changes that have occurred. Heightened clinical vigilance has been required as the laryngologist encounters new and unusual manifestations of the disease and must take more extensive histories regarding social, behavioral, and sexual practices than were previously necessary. The performance of physical examinations and surgical procedures has also changed as a result of experience with the lethal human immunodeficiency virus. Numerous legal, ethical, and social issues have also been raised by the epidemic and have had a major influence on how medicine is practiced and regulated. In this paper we review the laryngeal and pharyngeal manifestations of acquired immunodeficiency syndrome and discuss illustrative patient examples that demonstrate the impact of the disease. We also consider the diverse groups of issues that attend this epidemic and that continue to modify practice patterns.

KEY WORDS — acquired immunodeficiency syndrome, human immunodeficiency virus.

HISTORY OF ACQUIRED IMMUNODEFICIENCY SYNDROME EPIDEMIC

Human history has been marked with epidemics that have left indelible marks on society throughout time. Acquired immunodeficiency syndrome (AIDS) is a 20th-century example of an epidemic that has few limits and at present knows no cure. The media wrote and spoke of a "gay plague" in the early 1980s, and since that time society has been fervently struggling to combat AIDS. Laryngologists must specifically deal with AIDS because of the numerous manifestations of the disease in the head and neck region and the frequency with which AIDS phobia also presents in this region. Many of the current problems in dealing with AIDS are better understood if the history of the epidemic is reviewed and the difficulties encountered in recognizing the problem are stressed.

At the end of the first "AIDS decade" there are at least 10 million people worldwide infected with the AIDS virus. In this country more than 300,000 patients with AIDS have been reported and over 64% have died. Essentially, the 5-year mortality rate for AIDS patients from the time of diagnosis is greater than 90%. It is currently estimated that there are between 1 and 1.5 million people infected with the AIDS virus in the United States. For the year ending September 1991, there were 45,000 newly reported adult AIDS cases in this country. These are the reported cases and may or may not represent the total number, because of intentional or accidental underreporting. The disease occurs principally among homosexual and bisexual men, intravenous drug users, sexual partners and children of those infected, and recipients of contaminated blood and blood products. These have remained the high-risk groups throughout the last decade.

The apparent-inapparent disease ratio of human immunodeficiency virus (HIV) is not completely known. However, it is estimated that there may be as many as 50 times more HIV-infected individuals than there are actual cases of AIDS. Estimates are complicated by the long incubation period of AIDS, which may approach 7 to 10 years. It appears that AIDS will develop in at least 35% of HIV-infected persons. The outcome for the HIV-positive patients who do not currently have AIDS or AIDS-related complex (ARC) remains to be seen.[1]

The acquired immunodeficiency syndrome has also had a devastating effect on the health care system in the United States for several reasons: 1) the expenditure for patient care and the loss of economic productivity by the generally young patients have had a serious impact on the general and health care economies; 2) the disease has challenged all health care practitioners to study the modes of transmission of viral and other infections to provide care that is both safe and effective; and 3) AIDS has brought the numerous problems associated with the diagnosis and treatment of terminal illnesses to the fore in various scientific discussions.

The original patients who were reported to the Centers for Disease Control (CDC) were all young, previously healthy homosexual men with unusual

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opportunistic infections due to an unexplained suppression of the immune system.[2] The surveillance case definition for AIDS was first defined by the CDC in 1982 as the presence of opportunistic infections when no identifiable cause for cellular immune dysfunction existed.[3] This definition was created before the discovery of the AIDS virus, in order to consolidate, study, and report the constellation of signs and symptoms that were being encountered. The diagnosis of AIDS was based on the presence of 1 or more of 12 opportunistic illnesses, many of which are relevant to the laryngologist:

1. Atypical mycobacteriosis (disseminated).
2. Candidiasis (esophageal).
3. Cytomegalovirus (CMV) infection (pulmonary, gastrointestinal, or central nervous system).
4. Cryptococcosis (meningeal or disseminated).
5. Cryptosporidiosis (chronic enteritis).
6. Herpes simplex virus infection (chronic mucocutaneous or disseminated).
7. Kaposi's sarcoma (KS) in patients less than 60 years of age.
8. Papovavirus infection (progressive multifocal leukoencephalopathy).
9. *Pneumocystis carinii* pneumonia (PCP).
10. Primary lymphoma limited to the brain.
11. Strongyloidiasis (pulmonary, central nervous system, or disseminated).
12. Toxoplasmosis (encephalitis or disseminated).

Later, when the diagnostic serologic test was developed and more information became available, the definition of AIDS was modified to include other disorders. In 1987 the definition was further expanded to include enteropathic AIDS (HIV wasting syndrome), HIV encephalopathy, and others.[4] The term ARC refers to HIV-infected individuals who manifest some symptoms but do not meet the full criteria for AIDS. It has become evident that ARC is not a separate entity, but rather a part of the continuum between HIV infection and AIDS.

A viral illness caused by HIV, AIDS is transmitted by transfer of body fluids, principally by 3 main modes: sexual intercourse, especially receptive anal intercourse; transfusion of infected blood products; and perinatal transmission.[5] The term HIV has come to replace the former names, which include human T-cell lymphotrophic virus type III, lymphadenopathy-associated virus, and AIDS-associated retrovirus. Generally, AIDS has been recognized as a syndrome characterized by the presence of 1 or more opportunistic diseases that are indicative of an underlying cellular immunodeficiency, without any other known underlying cause of immunodeficiency. The causative agent for AIDS, HIV, is a retrovirus of the subfamily *Lentivirinae*. The term retrovirus is used because the virus contains the enzyme reverse transcriptase, which transcribes viral RNA into DNA — the reverse of other virus genetic transcription. Human immunodeficiency virus appears to be commonly lymphotrophic and primarily attacks T-helper cells, which are central to the function of the human cell-mediated immune system. Impairment of this function renders the patient susceptible to numerous opportunistic infections from viruses, fungi, and protozoa, many of which have been reported in the larynx, pharynx, and oral cavity. The full spectrum of pathologic consequences of HIV infection includes no disease, malignancies, infectious diseases, degenerative conditions, and various conditions with an autoimmune basis. It is postulated that tumors affect HIV-infected patients because the activation of certain oncogenes may be mediated by the presence of the added genome sequences.[6]

Retrospective investigation of the HIV epidemic has revealed that HIV probably entered the United States from central Africa by way of Europe or Haiti in the late 1970s. The first cases of what was later termed AIDS were reported to the CDC in the spring of 1981.[2,7] The report documented 5 cases of PCP in young homosexual men from California.

The Morbidity and Mortality Weekly Report (MMWR) on PCP sparked the researchers at the CDC in their own studies on sexually transmitted disease to think that PCP was somehow sexually transmitted in homosexual men, although no proof existed. Also in early 1981, several physicians in New York City were seeing patients with unusual perianal ulcers unresponsive to treatment. Many of these patients on both coasts also had *Candida albicans* or CMV infections, as well as debilitating fever, weight loss, and enlarged lymph nodes. Across the country anecdotal observations of rare diseases occurred throughout 1980 and 1981. The common thread to each of these cases seemed to be immunodeficiency of unknown cause. Siegal et al stated that some patients on both the East and West coasts were a "part of a nationwide epidemic of immunodeficiency among male homosexuals."[8(p1441)] The report of Siegal et al and the MMWR were the first publications to classify and group these disorders. Central nervous system cryptococcosis and toxoplasmosis were also being seen with some frequency, as well as

Mycobacterium avium-intracellulare. Cryptosporidium, which had only been reported 6 times nationwide from 1976 to 1981, was seen in 14 patients by 1 physician in New York City in 1981 and 1982.[9] It was at this time that we first diagnosed AIDS in a previously healthy young male Broadway dancer who presented with hoarseness and was noted to have candida in the larynx, pharynx, and oral cavity (see case 1).

Kaposi's sarcoma was another rare disorder that was being seen in many sexually promiscuous male patients who had also used "recreational" drugs such as cocaine, marijuana, lysergic acid diethylamide, and amyl nitrite. No obvious connection between drug use and KS existed, and again a sexually transmitted disorder was presented as the cause. Kaposi's sarcoma was previously almost unknown in men younger than 50 years old. The MMWR of the CDC reporting cases of PCP in gay men and disseminated KS infection in 19 gay men was published in the spring of 1981.[2] At this time, it was finally apparent that a nationwide problem existed.

At the National Institute Clinical Center, Fauci noted 2 interesting aspects of these disorders: a) unlike other opportunistic infections that generally affected people with broad-based immune suppression, the new disorders were more selective; and b) the T-4 cells lymphocytes were severely reduced or absent.[10] The immunoglobulin-producing cells, the B cells, were not suppressed but were actually hyperactive, although the effectiveness of these new immunoglobulins was poor. It was also noted that those suffering from KS alone had normal numbers of T cells, while those with PCP had virtually no T-helper cells.

Several different theories emerged regarding the cause of this immunodeficiency among homosexuals. One was centered on antigenic overload and took into account the large number of infections that the victims had had and suggested that recurrent infections lead to destruction of the immune system. Others challenged this theory and proposed that a new or transformed virus was responsible for the immune system failure.[11]

In 1982 these patterns of unusual infections in immunocompromised hosts were recognized in intravenous drug abusers (IVDAs) and blood transfusion recipients. Infants born to IVDAs in Newark, NJ, and Bronx, NY, were also becoming ill and dying of unusual opportunistic infections. Coincidence and investigation pointed to an acquired immunodeficiency as the cause. Sexual transmission was not a factor in these groups. It was later determined that HIV infection in children is primarily a disease of perinatal transmission (transplacental, during delivery, or postnatal).[12,13] When these cases were first diagnosed, HIV itself had not yet been identified.

At New York University, tracking the names of the sexual partners of the patients being seen with KS turned up 1 frequent name. Further investigation revealed that several of this man's other sexual partners had received diagnoses of or had died of AIDS. By accident this man was found in San Francisco, and with his cooperation the first firm evidence of a sexually transmissible agent was proved.

In 1983 and 1984 the putative agent responsible for AIDS was identified first in France and later the United States. Approximately 2 years later a serologic test, the enzyme-linked immunosorbent assay (ELISA), was developed to test for the presence of HIV antibodies. The test was very sensitive, and when it was combined with the highly specific Western blot test, the combined accuracy in diagnosing the presence of HIV antibodies was greater than 99%.

Although AIDS is a worldwide disorder, the epidemiology of AIDS worldwide is difficult to assess because of large gaps in information and because many countries use different surveillance systems. Cases have been reported in over 60 countries and over 5 continents. The disease is epidemic in central Africa. The prevalence data show that the disease is more widely distributed in heterosexual populations in Africa than in the United States or Europe. In Africa, men and women are affected equally, and the high-risk groups in the United States and Europe are not those of Africa. Rather, the spread of the disease in Africa is predominantly from heterosexual transmission, frequently related to the practices of female prostitutes.[14]

In the United States, the distribution of both AIDS cases and HIV infection of the 4 major risk groups can vary substantially by geographic area and age. Hemophiliacs (hemophilia A) have high levels of infection regardless of the area in which they live. The prevalence levels of HIV antibodies vary more among homosexual and bisexual men, with the highest levels in California and the Northeast and lower levels elsewhere.[15] Likewise, the prevalence of HIV infection among IVDAs varies widely, being highest in the metropolitan New York area and in Puerto Rico, moderately high elsewhere on the East Coast and in California, and generally below 5% in most other areas.

Both HIV infection and AIDS cases are largely a phenomenon of young adults. The infection rate is first appreciated in the middle to late teens, increases rapidly into the late 20s and 30s, and then declines in the 40s and 50s. The ratio of male to female cases is approximately 9 to 1. In the United States 64% of patients have been homosexual or bisexual men and 25% have been IVDAs. Approximately 3% of cases are due to receipt of contaminated blood or blood products. With regard to race, 58% of patients have been white, 27% black, and 15% Hispanic or other. Among IVDAs the male to female ratio is just greater than 3 to 1. In addition, AIDS cases among IVDAs are higher in blacks and Hispanics than in whites (2.5 to 1 and 1.4 to 1, respectively). Pediatric cases account for 1.7% of the approximately 200,000 affected individuals and constitute one of the most rapidly growing groups in the United States.[16]

The distribution of AIDS and its victims has slowly changed in the United States over the last decade. Initially, homosexual and bisexual men were by far the most commonly affected. The relative incidence is now increasing much more among heterosexuals. This change in case distribution has to do with education and the safer sex campaign that has been an integral part of the homosexual community for several years. The campaign has not made the same strides in penetrating the IVDA population, who frequently share needles and whose sexual practices are unprotected because of mental impairment.

The last major group to be affected by AIDS is the general heterosexual population. The risk factors for these people are sexual contact with a high-risk individual and unprotected sex with a presumed low-risk person who is HIV-positive. Although the risk of contracting HIV is small, it is growing. The CDC statistics show that newly reported cases of heterosexually transmitted AIDS have risen approximately 35% over the last year. Heterosexuals now account for between 6% and 7% of the total new adult cases reported by the CDC. This is different from the epidemic worldwide, in which 75% of cases are heterosexual.[17]

MANIFESTATIONS RELEVANT TO LARYNGOLOGY

The acquired immunodeficiency syndrome is of particular interest to the otolaryngologist–head and neck surgeon, since it has been estimated that 40% to 70% of patients present with a symptom or physical finding in the head and neck region.[17] These manifestations include various types of infection, inflammation, or tumor within the entire head and neck region. Oral cavity manifestations include candidiasis, KS of the mucous membranes, oral hairy leukoplakia, verrucae, and giant aphthous stomatitis. The esophagus may also be infected with candidiasis. The tracheobronchial tree may also be the site of infections that cause the patient to present with chronic cough and dyspnea, and PCP is one of the most common presentations in this regard. Cervical lymphadenopathy has also been commonly noted in patients with HIV infections. Various causes of the lymphadenopathy have been described.

Herpes zoster infections are due to reactivation of latent varicella zoster virus in the dorsal root ganglion, and the reaction phenomenon is thought to be secondary to deficient cell-mediated immunity. Friedman et al[18] reported that 73% of patients at high risk for AIDS who presented with herpes zoster were seropositive for HIV. An additional 15% became seropositive during the follow-up period. Herpes zoster infections in AIDS patients and in HIV-positive patients tend to be more severe than those in the general population. Oral acyclovir (Zovirax) may reduce the severity of the infection, as well as the severity of postherpetic neuralgia. Supportive treatment with other analgesics is also indicated.

An example of the increased severity of herpes infections is the recent recognition of giant herpetic oral, pharyngeal, and nasal ulcers, which have been reported in AIDS patients.[19] The ulcers begin in the nasal vestibule and extend onto the septum or the face, reaching a size of 3 cm or greater. Acyclovir is the treatment of choice.

The candidiasis observed in the nasopharynx, oral cavity, and larynx among AIDS patients is generally a manifestation of diffuse pharyngeal involvement by *Candida*. It most commonly presents in the typical pseudomembranous form with a cheesy white plaque that can be scraped off to reveal an erythematous base. Other forms that have been observed include an erythematous or atrophic form and a hyperplastic form. Around the mouth, *Candida* may present as angular cheilitis. Smear and culture are diagnostic. For treatment, oral ketoconazole is preferred to oral topical solutions, since they will not enter the nasopharynx.

Another manifestation of AIDS is the nasopharyngeal lymphoid proliferation that we reported in 1990 as a presenting sign of HIV infection.[20] In that series, all patients presented with the complaint of nasal obstruction. In addition, some had serous otitis media. Nasopharyngoscopy demonstrated mucosal-covered lymphoid masses that generally occluded the posterior choanae. Biopsy revealed benign lymphoid hypertrophy. Although giant cells were seen in some specimens, the significance of this finding is unclear. Excision of the hypertrophied lymphoid tissue relieves symptoms, but does not necessarily have any long-term benefit. The finding of lymphoid hyperplasia in a young adult patient who presents with the recent onset of nasal obstruction is strongly suggestive of HIV infection.

Various forms of lymphoma have been reported in the head and neck region. Although few cases of laryngopharyngeal lymphoma have been reported in general, we recently encountered an AIDS patient with an ulcerated lesion of the pyriform sinus that proved to be lymphoma on biopsy (case 4).

Before the AIDS epidemic, KS was a rare skin tumor that usually presented as a reddish blue nodule involving the skin of the lower extremities of elderly patients. However, with the onset of AIDS, KS has been demonstrated throughout the upper aerodigestive tract, as well as on the skin of the head and neck regions. In 1987, we treated a young patient with a large pedunculated KS lesion of the posterior pharyngeal wall that produced intermittent laryngeal blockage and necessitated tracheotomy (case 6). Kaposi's sarcoma is particularly fulminant among AIDS patients, with as many as 47% having pulmonary involvement at autopsy.[21]

We have recently reviewed our experience with KS among AIDS patients from January 1982 through May 1990 at Kings County Hospital Center, a 1,300-bed municipal hospital in the center of Brooklyn. In our series of 48 patients (unpublished observations, 1991), 30 had symptoms and signs in the head and neck region, including 16 in the facial skin, 4 in the cervical skin, 9 in the oral mucosa, 5 in the pharyngeal or laryngeal mucosa, 3 in the nasal mucosa, and 4 in the cervical lymph nodes. Some of our laryngeal findings were similar to those reported in a single case by Levy and Tansek.[22] They described a young bisexual man who presented with hoarseness and had a horseshoe lesion of the true vocal cords. The patient died 3 months later of other causes. There was no progression of the laryngeal lesion.

Emery et al[23] have called attention to the radiographic findings of pharyngeal involvement in KS in AIDS patients. In their series, barium pharyngography in 6 patients demonstrated nodular lesions without ulceration, ranging in extent from a single nodule to extensive confluent disease. In 2 patients who underwent computed tomography scanning, this modality demonstrated nodular or polypoid intraluminal protrusions, distortion of the valleculae and pyriform sinuses, infiltration of deep tissue planes, and adenopathy. They noted that radiographic evaluation was useful in assessing the lower extent of lesions that could not be fully assessed by visual inspection. Computed tomography aided in determining deeper plane involvement and nodal disease.

Various forms of therapy have been used for laryngeal and pharyngeal KS. Patients with impending respiratory obstruction (such as in our case 6) may require emergency tracheotomy. Patients with superficial or asymptomatic lesions may require no therapy at all. However, there is some evidence that radiotherapy[24] and the carbon dioxide laser[25] may each have a palliative role.

Another laryngeal manifestation that has been noted with increasing frequency is CMV infection. Small et al[26] called attention to laryngeal involvement by CMV in 1989 and indicated that it should be considered in AIDS patients with hoarseness. Siegel et al[27] subsequently reported a case of CMV laryngitis and probable coincident non-Hodgkin's lymphoma in an AIDS patient who presented with hoarseness and dysphagia. Marelli et al[28] stressed that although this important viral opportunist more commonly involves the eye or gastrointestinal tract, it is also found in the larynx. Accurate histopathologic diagnosis on material obtained by thorough biopsy is essential, since the treatment involves long-term therapy with a relatively toxic drug, ganciclovir sodium.[28]

Among the other laryngeal manifestations that have been reported in immunocompromised patients are invasive fungal infections,[29] laryngeal granuloma,[30] epiglottitis,[31] and laryngeal carcinoma.[32] The last disease may not specifically be a manifestation of HIV infection, but the clinical behavior of the tumors is somewhat different from that of tumors in non–HIV-positive patients (see case 9) and suggests that further study of a possible relationship is warranted.

Among the other areas of interest to laryngologists are the various tracheobronchial and esophageal manifestations of AIDS, since we are involved in the routine of complete endoscopy. In 1988, we reviewed our experience with 396 AIDS patients who were admitted to Lincoln Hospital, a municipal hospital in the South Bronx region of New York City.[33] The most common admitting complaints were related to pulmonary abnormalities and included cough, shortness of breath, and chest pain. Other common complaints of specific interest to the bronchoesophagologist included dysphagia and weight loss. On admission, 226 patients (57%) had clinical and radiographic evidence of pneumonia. Of these in whom a pathogen was isolated, the most common organisms were *P carinii* (138 patients or 61%), *Mycobacterium tuberculosis* (60 or 27%), and *Pneumococcus* species (18 or 8%). Among the other pulmonary organisms isolated were *Coccidioides, Toxoplasma, Candida, Staphylococcus, Histoplasma, Pseudomonas,* and *Streptococcus* species. No organism was isolated in 29 (13%). Forty (18%) of those patients with pneumonia had 2 or more pathogens isolated. Twenty patients had both *M tuberculosis* and *P carinii*. Ninety patients underwent fiberoptic bronchoscopy, transbronchial biopsy, and bronchoalveolar lavage, and 12 patients underwent rigid bronchoscopy. Eight patients required tracheostomies.

Also, 133 patients (34%) had documented candidiasis. Only 7 of these patients underwent esophagoscopy for diagnosis of *Candida* esophagitis. In this patient group, we also observed numerous cases of KS in the oral cavity, along with sporadic cases of giant intraoral ulcers, herpes simplex stomatitis, and oral hairy leukoplakia. These oral and oropharyngeal manifestations are of concern to the laryngologist and deserve comment.

Hairy leukoplakia is a form of leukoplakia that shows fibrillar projections extending outward from the surface of the lesion. Electron microscopic examination has revealed Epstein-Barr virus and papillomavirus in these lesions.[34] Herpes simplex is characterized by vesicles on an erythematous base and may present on the vermilion border or the oral mucosa. Giant intraoral ulcers measuring 1 to 4 cm in diameter have also been reported.[35] Their cause is unclear.

Oral laryngeal or pharyngeal candidiasis is uncommon in healthy individuals who have not received steroid or antibiotic treatment and may indicate the presence of AIDS or ARC. In its most typical pseudomembranous form, candidiasis usually can be recognized readily by its characteristic cheesy white plaques that can be scraped off, leaving an erythematous base. The diagnosis can be confirmed by smear and culture. Some less characteristic variants of candidiasis have been recognized, including a hyperplastic form that does not scrape off, an erythematous or atrophic form, and a form that presents as angular cheilitis.[35] In a study by Klein et al,[36] 59% of previously healthy patients with oral candidiasis had a major opportunistic infection or KS at a median of 3 months. Of 22 patients with ARC (generalized lymphadenopathy, fever, weakness, weight loss, and diarrhea) without oral candidiasis, none developed AIDS at a median length of follow-up of 12 months.

Oral or oropharyngeal candidiasis has been reported as a marker for esophageal candidiasis. In a study by Tavitan et al[37] of 10 patients with AIDS and oral candidiasis who underwent esophagoscopy, all 10 were found to have esophageal candidiasis. Seven patients complained of odynophagia, 1 patient complained of dysphagia, and 3 patients were asymptomatic. The authors concluded that lack of esophageal symptoms in a patient with AIDS and oral candidiasis does not exclude esophageal involvement. They recommended a 5-day trial of treatment for esophageal candidiasis in patients with AIDS and oral candidiasis. We prefer to initiate treatment with oral nystatin, and only if the symptoms persist after 5 days does the patient undergo diagnostic esophagoscopy.

In patients with laryngopharyngeal candidiasis, endoscopy generally has demonstrated diffuse mucosal ulcers with the characteristic cheesy white fungal debris on the surface. However, in a study by Farman et al,[38] 4 of 25 patients with esophageal candidiasis had localized lesions of the esophagus, as opposed to the usual diffuse involvement. Other organisms found to cause esophagitis include CMV,[39] *Cryptosporidium*, and *M avium-intracellulare*.[40]

The diagnosis of AIDS is frequently made because of the opportunistic pulmonary infections that account for almost 50% of initial presentations.[41] Approximately 85% of pulmonary infections in patients with AIDS are due to PCP. Often the patient presents with a prolonged history of dry cough and breathlessness. Patients also complain of an inability to take a deep breath and chest discomfort when they try to do so. This insidious onset is in contrast to the acute onset of most bacterial pneumonias. As a result, this condition is a particular challenge to the laryngologist, who may be asked to perform a laryngoscopy to aid in determining whether the respiratory symptoms are originating in the upper or lower airway. The chest radiograph on admission may appear to be normal. Initial radiographic changes may begin as a perihilar haze that may progress to diffuse symmetric shadowing of the middle and lower lung fields with peripheral sparing.

The diagnosis of PCP can be made by histologic examination of transbronchial biopsy, bronchoalveolar lavage, and induced sputum samples. Recently, it has been reported that examination of sputum induced by inhalation of 3% saline and stained with Giemsa stain or methenamine silver is able to detect greater than 50% of cases of PCP.[42,43] The diagnostic yield of transbronchial biopsy and bronchoalveolar lavage is 88% and 85%, respectively, and 94% when both procedures are combined.[44] A logical diagnostic approach to the patient with suspected PCP would be to obtain induced sputum samples initially. If they are found to be negative, then transbronchial biopsy and/or bronchoalveolar lavage should be performed.

Other infections and tumors that have been found to cause pulmonary disease in AIDS patients include CMV,[45,46] *M avium-intracellulare*,[47] *M tuberculosis*,[48] *Cryptococcus neoformans*,[49] *Histoplasma*,[50] *Toxoplasma*,[51] *Candida*, bacterial pneumonia,[52] and KS.[53] Cytomegalovirus as a sole cause for pneumonitis is unusual in patients with AIDS. It is more commonly seen in conjunction with PCP. In our series 18% of patients with pneumonia had more than 1 pathogen, and 9% of patients with pneumonia had tuberculosis and PCP. Because of the possibility of the coexistence of several pathogenic organisms, repeat bronchoscopy should be considered for patients who are unresponsive to treatment for the first organism isolated.[54]

In summary, the manifestations of HIV infection in the regions of interest to the laryngologist include a few common and many unusual types, some of which have previously been encountered as primary or secondary diseases, and others of which appear to be unique to AIDS. As the experience with this epidemic continues, it is important to be cognizant of the current manifestations, as well as to be vigilant in looking for any other evidence of the immune deficiency state that might indicate the need for appropriate testing.

CASE REPORTS

During the past decade our departments have encountered hundreds of patients with AIDS, AIDS phobia, and other conditions relevant to understanding this epidemic. The presentation of 11 selected case histories will exemplify some of the clinical and administrative issues relevant to the practice of laryngology.

CASE 1

The first patient encountered in our department was a previously healthy young homosexual male Broadway dancer who presented in December 1982 with hoarseness, dysphagia, and clinical evidence of oral candidiasis. Fiberoptic examination of the larynx demonstrated *Candida* of the epiglottis. Having just heard about the new AIDS problem, we contacted the head of the immunology service. He listened to the patient description and said, "It sounds like AIDS and he will be dead in 6 months." With that information at hand we elected not to inform the patient of the diagnosis until after he returned from a Christmas trip to visit his family. The patient returned to the office in January and subsequently was referred to the immunology service for treatment. He died in April 1983.

Comment. This patient illustrates the fact that as soon as the diagnosis of AIDS (or even HIV positivity) is made, both the physician and patient must prepare for the eventual fatal outcome of the disease.

CASE 2

An extremely debilitated 52-year-old male homosexual presented with an obstructive lesion in the nasopharynx that hung down behind the palate and was visible in the oral cavity. His diagnosis of AIDS was well established, and he requested symptomatic relief of the nasal and pharyngeal obstruction. We recommended excisional biopsy of the nasopharyngeal mass and enrollment in one of the experimental protocol studies being conducted. Unfortunately, his disease progressed rapidly and the patient returned to his home in South America for terminal care.

Comment. The patient illustrates the need for attempting to provide supportive care when medical intervention will not be beneficial, and for recommending that terminal care be provided in a familiar and supportive environment.

CASE 3

A 52-year-old male salesman had been followed up in the office for over 1 year with small laryngeal nodules that were monitored by fiberoptic laryngoscopy every 3 months. He came to the office the same day as the case 2 patient (above) and was the next patient to enter the examining room when that patient left. He inquired about whether that patient had AIDS. When we indicated that this information could not be given to him, he stated that he would allow a mirror examination but would not permit fiberoptic laryngoscopy, even though he was sure that the instruments were "probably clean."

Comment. Experience with this patient caused our office to design a private and expeditious arrangement for AIDS patients who were debilitated so that they would not be inconvenienced and other patients would not be frightened.

CASE 4

A 43-year-old known AIDS patient presented with a 9-week history of dysphagia, intermittent hoarseness, and severe throat pain radiating to the left ear. Two previous otolaryngologists had been unable to make a diagnosis, but neither had examined his pharynx by fiberoptic laryngoscopy. Use of this scope demonstrated an ulcerated mass in the left superior hypopharynx, extending into the anterior wall of the pyriform sinus. Biopsy was recommended, but the patient declined because he was in the middle of a protocol that would have to be interrupted for endoscopy. It was only after several lengthy discussions emphasizing the need for a tissue diagnosis in order to institute more specific therapy that he consented. The biopsy demonstrated malignant lymphoma (large-cell type). His previous protocol was discontinued and specific antilymphoma therapy was started. The referring internist found it difficult to understand why the 2 previous otolaryngologists were unable to find a very obvious lesion.

Comment. In this patient's care the role of the laryngologist was to make a specific diagnosis that would allow for optimal therapy. It required intruding into an existing therapeutic plan and stressing the need for an endoscopic procedure that the internist felt to be unnecessary. When the lesion causing pain was discovered it was necessary to explain the possible reasons for previous incomplete examinations.

CASE 5

A 60-year-old homosexual male was referred with hoarseness, dysphagia, and cough and was suspected by his internist of having KS of the larynx or pharynx. On fiberoptic laryngoscopy a mass was noted at the base of the left aryepiglottic fold and arytenoid. Biopsy demonstrated squamous cell carcinoma. The patient underwent total laryngectomy and subsequently required radical neck dissection after a metastatic node appeared. He has been followed up for over 1 year with no evidence of persistent or recurrent disease. When asked to provide a statement about his experience in dealing with the combination of laryngeal cancer and AIDS, he wrote the following.

> I learned I was HIV-positive in July 1990. Late the following January I underwent a laryngectomy, and this was followed in July by a second operation for neck cancer followed by 6 weeks of radiation treatment. I attribute my rapid recovery to a couple of factors. First, of course, the superior quality of my surgeon. Second, I had met a man the previous summer who had had a laryngectomy and he was perfectly well adjusted. (As he said, "Consider the alternative.") Third, I believe I have always had a rosy outlook on life and what it brings. This is in no way attributable to any effort on my part—I was born with my mother's angelic disposition and therefore very lucky. I'm sure this helped me take the news of my HIV condition with equanimity. The fact that I have an excellent AIDS specialist as my doctor I believe has reassured me. I have recently learned about the efficacy of Chinese herbs in treating HIV-positive people and I am extremely encouraged. I believe now there is no reason why I shouldn't live as long as most people.

Comment. Patients with AIDS can develop any other conditions, and it is not appropriate to assume that each symptom or physical finding is the result of immunodeficiency. In many instances the head and neck disease will be treated the same in the AIDS patient as in the non-AIDS patient.

CASE 6

A 22-year-old HIV-positive man had a bulky lesion of the posterior pharyngeal wall that was hanging into the laryngeal inlet and producing chronic cough. The patient almost had an obstruction when placed in the supine position, and an urgent tracheotomy was performed in a semisitting position. The procedure was greatly complicated by the lack of understanding of the appropriate guidelines for performance of surgery and a pervasive sense of fear among the operating room staff. The operating room walls were draped with plastic, only a minimal set of instruments was supplied, and the most junior scrub nurse was assigned to the case. The tracheotomy was successfully performed and the patient was then transferred to a full-service hospital for further therapy.

Comment. This was the first urgent tracheotomy performed at this institution on an AIDS patient. The near-panic state of the operating room staff threatened to compromise the delivery of optimal patient care. Subsequently, educational sessions were conducted to inform the staff on how to reduce risks and offer competent and safe care.

CASES 7 AND 8

A 31-year-old Hispanic man with AIDS presented with hoarseness. Fiberoptic laryngoscopy demonstrated a bulky mass of the posterior half of the right vocal cord and right arytenoid. The preoperative diagnosis was squamous cell carcinoma, but biopsy demonstrated cytomegalic inclusion cysts. The patient died 6 months later of severe CMV pneumonia.

A 42-year-old black woman with AIDS presented with a 6-month history of hoarseness and a 3-day history of respiratory distress. Fiberoptic laryngoscopy showed a large mass of the posterior larynx involving both arytenoids, both aryepiglottic folds, and the interarytenoid region. There was a white exudate on the surface of the mass. The preoperative diagnosis was squamous cell carcinoma with possible candidiasis. In the operating room the patient could not be intubated, and an emergency tracheotomy was quickly performed. Biopsy demonstrated CMV. The patient died 4 months later.

Comment. These 2 patients demonstrate that lesions resembling squamous cell carcinoma can indeed be the result of other causes, some of which, such as CMV, are more characteristic of AIDS. The laryngologist must be prepared for safe emergency tracheotomy if the situation warrants it.

CASE 9

A 32-year-old HIV-positive patient without clinical evidence of AIDS presented with a transglottic carcinoma that required total laryngectomy.

Comment. This patient is one of 7 HIV-positive patients without AIDS whom we have recently encountered with laryngeal carcinoma. They have ranged in age from 32 to 55, and 5 were under the age of 45. Five were treated with surgery, and 2 with radiotherapy (1 of whom subsequently required laryngectomy because of severe laryngeal chondronecrosis). Half of the operated patients developed fistulas. This experience suggests that HIV-positive patients may show us a different pattern of laryngeal carcinoma and require alteration in therapy.

CASE 10

A 41-year-old homosexual male paralegal who was HIV-negative presented with a 1-year history of hoarseness and mild dysphagia. He smoked 1 pack of cigarettes per day and drank 3 cocktails each evening. Physical examination including fiberoptic laryngopharyngoscopy demonstrated the findings of chronic laryngitis with mild pharyngitis. There were no lesions suggestive of AIDS. Despite this fact it took lengthy explanations and repeated reassurance of several visits to assure the patient that there was no evidence of AIDS.

Comment. Patients from known AIDS risk groups have a heightened awareness of the significance of persistent symptoms and are prone to interpreting them as evidence of HIV infection. The need for explanation and reassurance frequently goes beyond what is usually required for patients who are generally young and otherwise healthy. The appreciation of their fears is important.

CASE 11

A 22-year-old female secretary presented with recurrent episodes of hoarseness, throat pain, dysphagia, and symptoms of globus hystericus. Complete physical examination and endoscopy failed to reveal any significant disease. After lengthy discussion the patient volunteered that she had heard that recurrent infections or inflammations might be indicative of AIDS. Although she had no specific risk factors, she was advised to undergo HIV testing in order to provide a definitive answer.

Comment. Currently, AIDS phobia is replacing cancerophobia as a concern among patients even without obvious risks or characteristic lesions. This fact has a major impact on clinical practice.

An additional challenge that has appeared relates to AIDS-associated symptoms occurring in non–HIV-positive patients. The fear of AIDS has frequently been noted to bring knowledgeable patients to our office with subtle inquiries about whether an infection or other affliction might be a manifestation of immunodeficiency. Patients who have routinely tolerated minor infections or inflammations and who have often treated them on their own are now curious about why these infections are not responding. When confronted by patient fears of the possibility of being HIV-positive, it is prudent to recommend HIV testing, both immediately and again in 3 to 6 months. It is also worthwhile to caution the patient about suitable protective measures and to assure the patient of the physician's willingness to assist with these infections and with the attendant fears.[55]

The previous 11 cases are not meant to show any dominant themes of presentation or dictate therapy any more than any single case example does. However, they do exemplify the problems we have encountered repeatedly in the last 11 years of involvement with the AIDS epidemic. They also call attention to numerous patient care issues and related problems that merit review as we attempt to look toward the future of this broadening epidemic and its involvement with laryngological practice.

CLINICAL PRACTICE ISSUES

Review of our patient care experiences and relevant literature has prompted us to make numerous changes in the clinical practice of otolaryngology. They may be divided into several categories: 1) office practices and regulations of the Occupational Safety and Health Administration (OSHA), 2) specific protective measures, 3) operating room precautions, 4) instrument sterilization techniques, and 5) surgery in AIDS patients.

OFFICE PRACTICES

The AIDS epidemic has had an increasingly profound impact on the office practice of all branches of medicine, but especially laryngology. Logical concerns about prevention of transmission of virus between patient and physician emerged early in the epidemic, and the initial publications by the CDC were designed to address this issue. They focused on the universal precautions and were basically simple. Subsequently, in 1988, the State of New York Department of Health published "A Physician's Guide to AIDS: Issues in the Medical Office." This booklet devoted fewer than 4 pages to infection control, noted that there was no evidence of HIV transmission to health care workers (HCWs) from patients through casual contact or in routine office practice, and stressed the lability of HIV and its easy inactivation by simple disinfecting measures.[56]

With the escalation of the epidemic during the past 5 years, more attention has been paid to the exact nature of office practice precautions. Increasing focus on the consequences of the epidemic has been paralleled by increasing focus on the failure to practice medicine safely. This has culminated in the recent passage of a federal law referred to as the "Bloodborne Pathogens Standard,"[57] which applies to all occupational exposure to potentially infectious materials. It requires all employers covered by OSHA to develop a written exposure control plan; institute engineering and work practice controls; provide personal protection equipment, vaccination, and medical examinations; and institute annual training programs for employees. Virtually all physicians are affected by this law. The broad-ranging implications of this law may quickly be inferred by review of the summary provided by the Workplace Health and Safety Council in February 1992 (see Appendix).

The penalties for failure to observe this law are severe. Osguthorpe[58] recently reviewed the level of fines that can be assessed by an OSHA inspector or local health department surrogate, noting that there is a penalty of $7,000 for each infraction. Furthermore, "If an employee acquires HIV or a fatal HBV [hepatitis B virus] infection while performing duties in a medical office which is not in compliance with the OSHA guidelines, a $500,000 penalty is specified by OSHA, and the physician employer may be liable for the employee's health care and income until death."[58]

Dugan[59] and others have questioned the danger of medical waste and challenged the severe penalties involved in this area, but until future regulations are passed the existing federal law will obtain.

SPECIFIC PROTECTIVE MEASURES

The AIDS epidemic has prompted a thorough review of all facets of medical practice, particularly the avoidance of transferring contaminated material between individuals — whether it be from patient to HCW, from HCW to patient, or from patient to patient by exposure to unclean instruments. Since optimal protection is based on understanding the routes of transmission of HIV and their relevance to clinical practice, these routes will be reviewed.

The human immunodeficiency virus is transmitted primarily by percutaneous or transmucosal dissemination of infected material. In addition, transfusion of infected blood is the route generally implicated in dissemination of the disease among hemophiliacs. Perinatal transmission from mother to child occurs at or shortly after birth.

Because of the lability of the virus, a large inoculum of contaminated material or repeated exposure is necessary to transmit infection. No transmission has been attributed to ordinary social, household, casual, or occupational contact with AIDS patients or HIV-infected persons. These findings are relevant to the laryngologist, who must practice patterns of behavior that allow close and thoughtful contact with patients and simultaneously protect patient and HCW from needless contamination.

The universal precautions promulgated by the CDC[60] should be observed in routine practice. When followed universally, these basic precautions eliminate or significantly reduce the risk of transmission to the HCW, whether it be from a known AIDS patient or from someone who harbors the virus without evidence of clinical infection. The general guidelines are as follows.

1. Hand-washing is the most important means of preventing spread of infection. Personnel should wash their hands before and after taking care of patients, even when gloves are worn, since gloves do not always provide an effective barrier when they are presumably intact.
2. Gloves should be worn when there is any chance the hands will come into contact with blood, body fluids, secretions, or excretions.
3. Gloves should be removed as soon as the examination of each patient is completed. Gloves also should not come into contact with other objects or surfaces that may require subsequent cleaning.
4. Gowns should be worn when it is anticipated that clothing will become soiled with blood or body fluids. In routine office examinations, it is not necessary for HCWs to wear gowns, except when they must care for patients with epistaxis, whose blood frequently soils the HCW's clothing.
5. Masks are generally not necessary; however, when prolonged contact with patients who cough is anticipated (eg, during endoscopies or dental procedures), masks are recommended.
6. Protective eyewear should be worn for any procedure in which splashing or aerosolization of blood or body fluid is possible. This includes surgical procedures and endoscopies.
7. Special care should be taken in handling and disposing of sharp objects such as needles and knife blades. Needles should be discarded in rigid, puncture-proof containers rather than recapped. If recapping is necessary, the sheath should be laid on a table, rather than held in the hand, as the needle is carefully reinserted into it.

OPERATING ROOM PRECAUTIONS

In addition to the universal precautions disseminated by the CDC and the other recommendations listed above, there are other precautionary guidelines that pertain to the operating room setting for the laryngologist. In dealing with sharp instruments, particular attention must be paid to the possibility that they are contaminated with HIV. Since the rate of infection increases with the aliquot of blood to which one is exposed, one must obviously be more concerned with instruments that harbor more blood, such as hollow bore needles (as compared to solid needles, knives, and scissors).

The technique of instrument passage in the operating room has changed greatly as a result of the AIDS experience. In the past it was recommended (and taught in nursing schools) that each surgical instrument be placed firmly in the hand of the surgeon by the scrub nurse. This is still the case with nonsharp instruments. However, with sharp instruments it is recommended that they be placed on an instrument pad or Mayo stand for the surgeon to pick up and then returned to a pad or basin for the scrub nurse to retrieve. This method reduces the number of hand-to-hand transmittals of sharp instruments considerably.

Other sharp instruments such as scalpels and needles should be removed from the surgical field when not in use. Double-ended instruments with sharp ends, such as Senn rakes, are particularly dangerous and should be avoided or handled with special care. Also, single and double hooks, which may injure the scrub nurse or surgeon if not passed carefully, require scrutiny. In many instances, retraction of cervical tissues can be achieved as well by use of blunt retractors or Allis clamps as by hooks.

Gloves have received special attention in the AIDS epidemic. Although various types of thicker gloves have been studied, and double-gloving has been recommended in many instances, it is clear that the surgeon must attend to the risks involved in routine glove use. It has been well documented that gloves are not an absolute barrier to infection. If a glove is torn or violated during surgery the surgeon should drop out, deglove, inspect the area of possible injury, and rescrub before regloving. This procedure will reduce the risk of infection.

Although no case of transconjunctival infection has been reported, it is prudent to pay attention to guidelines for protection of the eyes. It is recommended that eye protection be provided during laryngoscopy and bronchoscopy under local anesthesia, since aerosolization of potentially contaminated secretions is very likely. The same is true when the surgeon is drilling in a wet field such as with mastoid surgery or plating.

INSTRUMENT STERILIZATION

The sterilization and care of instruments used in office and operative procedures involving the larynx, pharynx, and oral cavity deserves special attention. Laryngologists use instruments such as tongue blades, mirrors, suctions, flexible fiberoptic nasopharyngolaryngoscopes, and others that require special care to maintain their usefulness, as well as to protect the patients who are being examined and other patients on whom the instruments are subsequently used. This requires attention to the issues of sterilization and disinfection.

Sterilization is the use of physical or chemical procedures to destroy all microbial life, including those organisms that exist on inanimate objects. Disinfection is a less lethal process that destroys all recognized pathogenic microorganisms, but does not necessarily destroy all microbial forms, such as spores. Spaulding[61] has divided disinfection into 3 categories based on the types of microbial life destroyed. High-level disinfectants are active against vegetative bacteria, tubercle bacilli, fungi, viruses, and spores. Examples include 2% aqueous glutaraldehyde, 8% formaldehyde solution in 70% alcohol, 6% to 10% stabilized hydrogen peroxide, and ethyl oxide gas. Intermediate-level disinfectants are active against vegetative bacteria, tubercle bacilli, fungi, and viruses, but are inactive against spores. Examples include 0.5% iodine, 70% to 90% ethanol or isopropanol, and chlorine compounds. Low-level disinfectants are active against vegetative bacteria and fungi, but are inactive against bacilli, viruses, and spores. Examples include quaternary ammonium compounds and mercurial compounds. Since AIDS is transmitted by HIV, it is clear that a high- or intermediate-level disinfectant should be used rather than a low-level disinfectant.

In choosing a sterilizing method for laryngologic instruments, one must distinguish between physical and chemical sterilants.[62] Chemical sterilants include ethylene oxide, glutaraldehyde, formaldehyde, stabilized hydrogen peroxide, iodophor iodine, chlorine compounds, phenolic compounds, quaternary ammonium compounds, and mercurial compounds. Physical sterilants include steam, ultraviolet radiation, and ionizing radiation. Heat is one of the oldest and most recognized sterilizing agents and may be used in either a moist or dry form. Dry heat is relatively slow and requires higher temperatures. Steam sterilization is generally a safe and practical means of sterilizing surgical instruments. However, thermoplastics such as polyvinyl chloride, which is used as a coating on some instruments such as most flexible laryngoscopes, can deform under the pressure and temperatures used in steam sterilization.[62] Ultraviolet light is also effective in killing bacteria, viruses, and molds. However, it does not penetrate most substances and therefore is used for destruction of airborne organisms, as well as organisms located on surfaces accessible to ultraviolet light. Ionizing radiation, either electron beam or gamma radiation, produces bacteriocidal effects by transferring the energy of a photon into characteristic ionizations in or near a biologic target, thereby producing free radicals and activated molecules. Radiation sterilization is an established industrial process, but it is relatively inaccessible to hospitals.

In choosing the form of sterilization, one must consider the likelihood of contamination of instruments and the uses to which they will be put, since not every instrument requires the highest degree of sterilization. Spaulding[61] has divided medical instruments into 3 categories: critical, semicritical, and noncritical. These categories are based on the degree to which the risk of infection is involved in their use. Critical items are instruments that come into direct contact with blood or sterile areas of the body and thereby pose a high risk to patients. These items include scalpels, forceps, and implants. They must be sterile before use. Semicritical items are those that come into contact with intact mucous membranes but do not penetrate body surfaces. They include flexible fiberoptic endoscopes and endotracheal tubes. In most instances, meticulous physical cleaning, followed by the use of a high-level disinfectant, ensures that the instrument will be free of pathogenic organisms. Noncritical items are those that come into contact with unbroken skin. They include face masks, stethoscopes, and electrocardiogram electrodes. Generally, cleaning with a good detergent and hot water is sufficient. Many of these items are disposable.

Microbiologic studies indicate that HIV is susceptible to chemical disinfectants. It is also susceptible to heat inactivation, although the length of time required for thermal inactivation of the virion has been debated.[63-66] Among other agents that have been reported to decontaminate HIV-exposed instruments are 50% ethyl alcohol, 35% isopropyl alcohol, 10% household bleach, 0.3% hydrogen peroxide, and 2% glutaraldehyde.

In choosing a method for sterilization of a flexible fiberoptic nasopharyngolaryngoscope, one hopes to kill all organisms, avoid harm to the instrument and its coating, and achieve the sterilization process quickly so that it will not be necessary to have numerous instruments available. No currently available sterilizing agent optimally meets all of these criteria. However, the use of 2% glutaraldehyde has been recommended by the CDC and adopted by our institution for sterilization of flexible nasopharyngolaryngoscopes. After each use, the endoscope is manually cleaned by wiping it with an alcohol sponge. This removes any secretions and organic matter before disinfection. The endoscope is then immersed in 2% glutaraldehyde for 10 minutes. After that time, the endoscope is rinsed with water and air dried before storage or further use. Rinsing off the glutaraldehyde is important to avoid dissolving the endoscope's coating, as well as to avoid the irritating effects of glutaraldehyde on the nasal mucosa.

Other instruments used in laryngologic procedures are also sterilized in glutaraldehyde after preliminary manual cleaning. Particular attention should be paid to light-carrier channels in hollow endoscopes and to the hinges and inner surfaces of cup forceps, which require meticulous mechanical cleaning. When suction tips, which may not be penetrated by liquid solutions, are used, it is important to aspirate a small amount of the disinfectant into the suction tube before soaking the tube in the liquid. Special care must be taken when using brushes in the lumen of hollow laryngoscopes in order to prevent aerosolization of bloody or contaminated debris located in the inner surfaces of the instruments.

In summary, the advent of the AIDS epidemic has caused HCWs to examine instrument cleaning and sterilization in a way that has probably not received adequate attention before. The fear surrounding this epidemic has developed into a productive evaluation of the sterilization methods employed in the office and the operating room. This evaluation will probably extend to more careful sterilization of instruments used for other procedures and for other regions of the body. Careful sterilization of instruments should prevent contamination from other infectious diseases as well.

SURGERY IN AIDS PATIENTS

Much attention has been focused on the indications for surgery in patients with AIDS. Much of the concern is probably unnecessary. If universal precautions are followed carefully for all patients, the risk to HCWs who operate on AIDS patients should be no greater than the risks encountered in operating on patients who are not HIV-positive. There are several issues to be examined in determining a policy for surgery in AIDS patients. They include the urgency or necessity for surgery, the likelihood of risk to the surgeon or other members of the surgical team, the risk the surgical procedure poses to the patients themselves, and the specific modifications in surgical procedures and techniques that can make the operating room experience safer for personnel and patients, regardless of their HIV status.

With regard to the necessity for surgery it is presumed that all recommended surgery in any patient is necessary (with the possible exception of elective cosmetic surgery). With that stipulation in mind, it is currently the feeling that careful observance of the universal precautions and the other specific recommendations listed above will be sufficient to create a relatively safe environment for surgery. The risks to the surgical team are best controlled by creating a team of informed surgeons and assistants who perform every procedure as if the patient is HIV-positive. The actual risks have been documented in various publications and related primarily to the simultaneous presence of several moving hands and several sharp instruments in the surgical field. The precautions are designed to reduce those circumstances.

In laryngology there are very few high-risk, exposure-prone procedures that threaten the surgeon. Endoscopic procedures entail little risk, unless aerosolization occurs because the patient under local anesthesia begins coughing out bloody secretions. Eye protection is advised in this circumstance. Major open procedures on the larynx, pharynx, and neck should always be performed with deliberate and controlled movements, regardless of the HIV status of the patient. The only 2 instances of abnormally high risk that occur to this author are the following: 1) performance of an emergency tracheotomy on a vigorously moving patient who cannot be sedated and 2) insertion of an epiglottic suspension suture in an obese patient following vertical partial laryngectomy, in which difficulty locating the needle point in the small incision and deep wound is a source of consternation and some risk. Otherwise, attention to standard precautions should provide a relatively safe environment for performance of surgery.

The ethical issues involved in performance of surgery and other aspects of care of AIDS patients are considered below, as are the issues of informed consent and physician-patient communication.

LEGAL AND SOCIOECONOMIC ISSUES

Among the most significant areas of change in the clinical practice of laryngology are those impacted by the myriad of legal and social issues that have been identified during the AIDS decade. They are currently being discussed actively in many forums. In many instances, there are no definitive answers available at this time. However, in an effort to provide information, we shall address a number of these issues and report on current considerations. It is not yet possible to prepare a comprehensive and cohesive statement resolving the numerous legal issues, but by referring to numerous published sources we find some guidance for the continued study of these problems during the coming years of practice.

In view of the finite amount of money available to support health care in the United States and the need for the medical professions to engage in the dialogue that affects the apportionment of these funds, it is important to examine the impact of AIDS. A recent major study by Hellinger[67] forecasting the medical care costs of the epidemic through 1994 estimated the lifetime costs of care for a person with AIDS at $85,333, and the average annual costs for HIV-positive individuals without AIDS at $5,150. He calculated the cost of caring for all persons with HIV to be $5.8 billion in 1991, rising to $10.4 billion in 1994.

These direct costs are in addition to the much greater financial burden produced by the removal of many productive people from the work force. The disease affects many professionals between the ages of 20 and 50. The economic impact of their loss of productivity is staggering.

Government entitlement programs bear the greatest share of the financial burden: Medicaid covers approximately 40% of people with AIDS, Medicare 2%, and private health insurance 29%. The remaining 29% have no insurance, although some of them receive health care directly from institutions such as prisons and the Department of Veterans Affairs.[68]

The costs of care for the AIDS patients with neither public nor private insurance are borne largely by public and teaching hospitals, some of which are experiencing significant financial losses. The magnitude of the inadequacy of existing financing mechanisms has led the National Commission on AIDS to call for universal health insurance. Clearly, the economic consequences will continue to present a major challenge for public policy.

Numerous legal issues have arisen in the AIDS epidemic, and this has already become the most litigated disease in American medical history. Among the most prominent issues are testing, reporting, and disclosure. Mandatory HIV testing or screening is a highly controversial issue. The principal objective of screening programs, namely protection of others from infection, is made more pressing by the fatal outcome of the disease.

However, screening is far from an ideal means of protection, since in order to be effective, it must be repeated at periodic, frequent intervals. Whether such repeated testing is cost-effective depends on a number of factors, including the prevalence of infection in the target population and the dollar and human costs of the test. Certain screening programs in Illinois and Louisiana proved not to be cost-effective and were discontinued.

Regardless of the costs of testing and of the fact that chemical analysis can only indicate whether the individual has developed HIV antibodies, not whether he or she is infected and infectious at the time of the test, interest in routine screening of patients remains high. The American Medical Association (AMA) has formally approved the concept, recommending that hospitals, clinics, and physicians adopt routine testing, depending on local circumstances and with the consent of the patient.[69]

Conversely, the National Commission on AIDS recently argued against widespread testing, stating, "Mass screening programs would interfere with the doctor-patient relationship, would encourage a false sense of security because of the time between when infection develops and the time when it can be measured by clinical tests, and would imply a significant risk of infection transmission in health care settings where such risk is actually very small, particularly, as CDC has stated, 'when HCWs adhere to recommended infection control procedures.'"[68(p53)]

The most important obstacle to routine or universal testing is the requirement of informed consent. Thirty-one states mandate informed consent for administration of an HIV test.[70] There have been many lawsuits brought alleging that the test has been performed without consent. These have occurred in the contexts of the judiciary, corrections, health care, public health, insurance, and industry, with inconsistent outcomes.[71]

Although it rejected the legislative proposals that would have eliminated the requirement of informed consent, the AMA did call for a simplification of consent procedures, stating that "patients at least should know about and be prepared for the HIV test and its implications. Informed consent also should include the assurance that medical care will not be denied if testing is declined."[72]

The testing of physicians and other HCWs has drawn much attention but remains controversial. Factors against mandatory testing include cost, uncertainty of test results due to delay in seroconversion, and the presumption that physicians are generally ethical and will voluntarily seek testing if they are at risk.[73]

One of the most difficult of the numerous new and special problems in clinical practice is that of the HIV-positive physician. It challenges the physician's co-workers, employees, and patients, as well as the physician. Among the questions raised in this regard are the following.

1. How commonly do physicians and other HCWs become HIV-positive, and by what mechanism?
2. Should physicians be routinely tested?
3. Should any professional activities be restricted?
4. What responsibilities do employers, hospital administrators, service chiefs, and co-workers have in dealing with HIV-positive physicians?

In the most recently published national surveillance update of HCWs with AIDS, Chamberland et al[74] noted that through June 30, 1990, there were 5,425 cases reported. This represented 4.8% of the 113,208 individuals over the age of 13 with AIDS reported as of that date, for whom information was available regarding employment in a health care setting. (Total cases as of that date were 137,385 in persons over 13.) Since HCWs constitute 6.0% of the US labor force, they do not appear to be either overrepresented or underrepresented among persons with AIDS. Of the HCW group, 5,120 (94.4%) had nonoccupational risks, with sexual practices far exceeding intravenous drug use as the dominant risk factor. In contrast with other epidemics with which physicians have been involved, such as plague and influenza, physicians have most commonly become infected with HIV, not by carrying out their professional duties, but by engaging in dangerous social practices.

In attempting to provide advice on this issue, the CDC made the following recommendations in the July 12, 1991, MMWR.[75]

1. Strict adherence to the previously published universal precautions.
2. No practice restrictions on HIV-positive HCWs who do not perform exposure-prone invasive procedures.
3. The identification of exposure-prone procedures by medical, surgical, and dental organizations and institutions at which the procedures are performed.
4. Knowledge of their HIV status by HCWs who perform exposure-prone procedures.
5. Advance approval for HIV-positive HCWs to perform exposure-prone procedures after the circumstances under which they are performed have been reviewed by an expert review panel. This panel might include such persons as the HCW's personal physician, an infectious disease specialist, a professional familiar with the procedures performed by the HCW, and state or local public

health officials. The panel must recognize the importance of confidentiality and the privacy rights of infected HCWs.

6. No mandatory HIV testing of HCWs.

Subsequently, other groups such as the AMA, American College of Surgeons, and various state and local departments of health issued similar recommendations. Most regulations stressed the individual responsibility of the individual physician to know and observe infection precautions and to seek voluntary HIV testing if at risk. Virtually no group has recommended routine testing of physicians.

There has been general consensus that infected physicians pose little risk to patients in routine office practice, but that they need careful scrutiny if performing high-risk, exposure-prone surgical procedures. The exact definition of such procedures in laryngology has not yet been determined. It is generally felt that few laryngeal procedures would qualify as high-risk and exposure-prone, with the possible exception of an emergency tracheotomy (in that it may require the simultaneous presence of several sharp instruments in a poorly exposed field).

The impact of real or perceived HIV positivity on the individual physician's practice is likely to be enormous. Daniels[76] recently compared the right of patients to be informed and protected from infection with the right of HIV-infected physicians (who now qualify as "handicapped" under The Americans With Disabilities Act of 1990 [ADA][77,78]) to practice medicine safely. Recognizing that patients may switch physicians for various real or perceived reasons, he urges a rational approach that stresses compliance with infection control measures, voluntary testing, and improved educational efforts to explain actual risks, rather than any programs or policies that facilitate switching.[76]

A case involving an otolaryngologist specifically demonstrates the problems involved in this area. In 1987, a medical center in New Jersey suspended an otolaryngologist's surgical privileges immediately on learning he was HIV-positive and within the year adopted a policy barring HIV-infected physicians from performing procedures posing any risk to patients. The hospital also imposed a requirement that HIV-infected physicians obtain specific written informed consent before performing invasive procedures — a requirement that some consider tautological given the prohibition on operations entailing any risk whatsoever to which the patient might need to assent.[73]

This physician died in 1989, having performed no surgery since his diagnosis of AIDS. The litigation brought by his estate against the hospital[79] presaged a number of the legal questions addressed by the CDC's July 1991 guidelines, and also by the ADA.

First, the court upheld the hospital's decision restricting the surgeon's privileges and requiring him to obtain his patients' written consent, ruling that there was no unlawful discrimination. The New Jersey Law Against Discrimination, like the ADA, allows differential treatment of the handicapped (including persons with AIDS) if their condition impinges on their job performance. The court found that the risk of the physician's infecting patients, although not established, was an adequate justification for differential treatment. Of particular interest to laryngologists is the court's noting that much of this physician's surgery involved contact with patients' mucous membranes, which heightens the risk of HIV transmission.

The new CDC recommendations for preventing transmission establish a much more lenient standard than did the New Jersey court, stating, "HCWs who are infected with HIV or HBV (and are HBeAg [hepatitis B antigen] positive) should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures."[80(p5)] There is no restriction, other than the recommendation to adhere to universal precautions, with respect to "invasive procedure[s] not identified as exposure-prone."[80(p5)]

The acknowledged experience and authority of the CDC are likely to persuade any future court facing a question of the permissible scope of practice restrictions to uphold hospital policies consistent with the CDC guidelines, and to reject policies that go further.[73]

The second major holding in the New Jersey case relates to the confidentiality of an HCW's serostatus. The New Jersey court ruled that the medical center had breached its duty by failing to take reasonable precautions to prevent the physician's diagnosis from becoming public, entitling his estate to monetary damages.

Privacy in the AIDS epidemic is of great importance to many physicians. In a survey conducted by the Medical Expertise Retention Program, an advocacy group for infected physicians, 73% of the 196 respondents indicated that they feared job loss if their status was known, and more than two thirds also stated that they had avoided seeking HIV treatment (or reimbursement for treatment) in order to avoid discovery.[81]

The CDC guidelines attempt to balance various principles and interests. They provide that HIV-positive physicians may continue to perform exposure-prone procedures with the advice of and under circumstances determined by an expert review panel. Those circumstances include prior notification of the HIV status to prospective patients, an option that appropriately leaves the disclosure decision up to the physician.

Other guidelines relevant to the problem of the HIV-positive physician are considered in the section on the OSHA regulations on blood-borne pathogens (above). This act clearly affirms the responsibility of employers to provide a safe workplace that protects employees from exposure. Various other issues relevant to the HIV-positive physician have been addressed by this author in another publication.[82]

OTHER PATIENT CARE ISSUES

Beyond the more immediate concerns of making diagnoses and formulating plans of treatment, the AIDS epidemic has prompted many physicians to review numerous complex issues related to patient care.[83] These include comprehensive social and cultural patient assessment, physician-patient communication, patient education, dealing with phobias, the impact of the care-rendering experience on the physician, and the involvement of the physician in terminal care. The laryngologist is involved in each of these areas, and the practice of laryngology will experience the effect of these issues.

FEAR OF AIDS

The AIDS epidemic that was first recognized in 1981 was quickly paralleled by a second epidemic: AIDS phobia. This term applies not to the justified concerns of perceptive observers who appreciate the lethal nature of the disease, but to the unfounded anxieties of those who do not understand the mechanisms of HIV transmission and the simple measures for protection from contamination. We have mentioned several examples in the above patient reports, but these phobias have also been directed at known AIDS patients who have been shunned by co-workers, at noninfected risk-group members who have lost employment or been denied community services, at infected children who have been banned from schools, and at parents of hemophiliacs who have suffered with their children.

The best mechanism for dealing with these anxieties, misunderstandings, and phobias is a broad-based educational program founded on the most current accurate information and interpreted with common sense.

PHYSICIAN-PATIENT COMMUNICATION

A firm physician-patient relationship is based on open and frank communication. In order for this to occur, both parties to the communication process must be comfortable and honest with each other. They must also try to understand each other. In many instances, the AIDS epidemic has brought a new dimension to this relationship, in that it has exposed physicians to numerous medically relevant social and behavioral characteristics and patterns with which they might have been unfamiliar. Increasingly, physicians have had to learn more about the lifestyles and sexual practices of their patients in order to make a more circumspect diagnosis and formulate a reasonable treatment plan. In addition, physicians who have been accustomed to dealing with traditional family constellations as a source of support to ill patients have had to learn to deal with patients whose support systems may be limited and may consist of persons who are similarly at risk for disease.

In examining the impact of AIDS on laryngological practice, we have noted certain patterns that have been mentioned in the case presentations and that merit repeating here.

Among the most important observations made in our patients is the fact that once the patient is aware of his or her diagnosis of AIDS or even of HIV positivity, the prospect of incurable illness and eventual death is foremost in the patient's mind. As a result the patient may manifest early on the various stages described by Kübler-Ross[84] as part of the dying process, namely denial and isolation, anger, bargaining, depression, and acceptance. The anger stage may be particularly difficult for the physician and office staff, as the patient may miss appointments, displace internal feelings to others, and generally act out the anger in a disruptive way.[84]

Another issue that the AIDS epidemic has brought forward concerns the need to take a more thorough social and sexual history than many laryngologists have done in the past. This issue is best addressed in a way that assures the patient of confidentiality and the genuine desire to help. Rather than asking directly, "Are you a homosexual?" or "Do you shoot drugs?" it is better to begin by asking, "Do you have any practices that place you at risk for AIDS?" If the patient does not understand, one can describe the modes of transmission, reassure the patient of the physician's discretion, and explain why the information can assist with more accurate diagnosis and effective therapy.

The AIDS patient is frequently under considerable stress. As a result, when communicating diagnoses and plans of therapy, whether related to the HIV infection or not, repeated explanations may be necessary. The presence of family members or friends who can later confirm the substance of the communications is helpful. Follow-up visits, written instructions, and assurance of the physician's continued availability and interest in the patient's welfare are also important.

Several of our patient examples illustrate the problems of a group called the "worried well," those with no evidence of disease but great anxiety about the possibility of infection. They may express their concerns by asking directly, "Is it possible that I have AIDS?" However, more commonly they will present a litany of complaints without any clearly professed diagnosis in mind. When this form of AIDS phobia is noted, it is helpful to deal with the situation in a manner similar to dealing with cancer phobia. This involves conducting a thorough clinical examination, listing and excluding the many diagnoses about which patients with similar complaints typically worry, and concluding with a statement such as "I see no evidence of cancer or of any of the serious infections about which one hears so much these days." With patients who are still concerned and secretive it may be worthwhile to offer HIV testing or to suggest that the patient may wish to consult an internist for a comprehensive examination.[83]

COUNTERTRANSFERENCE ISSUES

Countertransference is a term used in psychiatry to refer to the emotions or feelings engendered in physicians by their interaction with patients. Dunkel and Hatfield[85] have listed 7 examples of this phenomenon in the AIDS epidemic.

1. Fear of the unknown and fear of contagion.
2. Fear of dying and death.
3. Overidentification with the patient (since most AIDS patients are between 20 and 50 years old).
4. Guilt over helplessness.
5. Fear of homosexuality.
6. Anger (at a patient who may have acquired a disease by a self-destructive act or at an epidemic that challenges and disrupts traditional medical practice).
7. Challenge to the physician's sense of "omnipotence."

These unpleasant feelings can readily cause physicians to avoid the close and concerned contact that patients require and deserve. When this is the case it is helpful to discuss one's own reaction with colleagues who have been able to keep the feelings in perspective or to seek suitable professional advice from a psychiatrist or other counselor.

ETHICAL ISSUES

One of the major developments that have resulted from the AIDS epidemic is the reexamination of the ethical issues related to the practice of medicine. The practice of laryngology is a good example of the problems that have been noted.

A very thorough consideration of the various ethical issues has been presented by Pellegrino[86] in his classic paper "HIV Infection and the Ethics of Clinical Care." He raises 3 important questions.

1. Is there a moral obligation that compels physicians to treat patients with HIV infections even at risk to themselves?
2. If there is such a duty, in what ways, if any, is it modified by the universally fatal outcome of the disease?
3. How does a diagnosis of HIV infection affect treatment decisions and the vigor with which they are pursued?

The first question is critical, since it basically asks what the moral identity of any physician is. Noting that there is no single source for definitively answering this question, Pellegrino suggests that relevant answers may be found in 6 sources: professional ethics, the traditions of the profession, the character of the physician, general ethical principles, socially defined roles, and the internal morality of medicine.

Citing various sources ranging from the Hippocratic Oath to the AMA Principles, as interpreted by the Council on Ethical and Judicial Affairs,[87] he finds support for the obligation to treat. In examining the nature of the physician's character, he notes that all patients are eventually dependent on the virtue and character of the physician, but acknowledges that there is disagreement on whether duties to family, society, and other patients might preclude treatment of HIV infection.

The other sources cited support the notion of the duty to treat, but Pellegrino finds the strongest support in what he defines as the internal morality of medicine. He indicates that the physician has certain technical knowledge essential to healing and a coincident obligation to provide that knowledge when required. The specialized educational environment in which students and physicians learn by invading the human body and gain hands-on education in subsequent house staff training is tolerated and supported by society with the understanding that the skills gained will benefit the sick. He states that "medical knowledge is knowledge held in trust for the benefit of the sick. Knowledge gained in this way justifies itself only when it is employed for the good of others."[86(p36)] Taking the 6 sources of information listed above cumulatively, Pellegrino favors a strong position obligating physicians to treat all patients.

With regard to the question of whether the fatal outcome of HIV infection modifies the duty to treat, he finds no extraordinary risks to the physician that mandate changing standard treatment modalities if physicians follow the well-promulgated precautionary measures. However, he acknowledges that the emotional stress may require temporary relief from duty, just as in combat service during wartime.

After considering the duties of the physician, Pellegrino[86] notes that patients, hospitals, and society also have duties that may include testing, enhanced measures for confidentiality, and provision of support to patients found to be HIV-positive. He states that organized medicine has responsibilities to physicians that may include defining obligations, providing educational support, and distributing the burdens of treatment over the entire medical profession.

With regard to the third question, namely whether the fatal outcome of HIV infection modifies medical judgment and treatment intensity, Pellegrino[86] recommends that guidelines used in other fatal diseases are relevant and that treatment be delivered, withheld, or withdrawn on the basis of prognosis, effectiveness, and benefit of treatment and the patient's consent, rather than on the eventual outcome of the disease.

Although individuals and organizations may take issue with the points raised by Pellegrino, he has unquestionably done the profession a tremendous service by providing such a clear analysis. The impact of the ethical issues discussed is clearly evident in the practice of laryngology and varies from such instances as choosing to accept an AIDS patient who presents for evaluation of hoarseness to managing laryngeal carcinoma in an HIV-positive patient.[88]

CONCLUSION

In summary, we have reviewed the history of the AIDS epidemic, listed the various manifestations in the larynx and pharynx, reported our experience with several large series of patients, and described 11 illustrative patients. The lessons from these individual patients encapsulate the lessons from the epidemic to date, namely the need for scrutiny of all aspects of clinical practice. The otolaryngologist is well advised to evaluate all activities in the light of this epidemic, with the goals of providing safe and concerned care to patients, as well as avoiding needless risks to co-workers, other patients, and self.

Although most laryngologists will not be extensively involved in the long-term management of AIDS patients, all will experience significant impact from the epidemic. The great frequency with which HIV infection manifests in the head and neck region will challenge diagnostic skills. The most common modes of transmission require thorough history-taking procedures that may be different from those ordinarily employed in laryngeal practice.

Clinical practices in the office and operating room are changing greatly in response to the information about the methods of reducing the risk of infection and the stringent regulations that have been enacted. Although the laryngologist rarely performs procedures that would be classified as high-risk or exposure-prone, he or she must now attend to all of the details of waste disposal, instrument sterilization, and employee safety.

It is important to keep AIDS in perspective when laryngeal surgery and office procedures are contemplated. Physicians are advised to reexamine all circumstances involved in office and operating room activities to determine how best to observe universal precautions. The limitations and restrictions on testing (many of which are prompted by complex social and political factors) prevent widespread testing procedures, particularly since confidentiality of results cannot be ensured and interpretation of results is open to error.

In the future all physicians will be increasingly called upon to fulfill the ethical responsibilities of their profession by offering concerned, efficient, and conscientious care to diverse groups of patients whom we may poorly understand. Availability throughout the course of the patient's disease is critical. This continued involvement may be stressful for the surgeon who is accustomed to performing a procedure and concluding a contractual relationship within a defined period of time. It is also uncomfortable for the physician who may experience the countertransference feelings listed above. However, failure to offer one's best efforts is an abrogation of the physician's primary responsibility to society — namely, to provide one's best skills selflessly to those who seek them.

Decades ago syphilis was called the "great imitator." Now AIDS might aptly be called both the "great intimidator" and the "great educator." To recoil from the intimidating impact of the epidemic and to withdraw from involved patient care would be inappropriate. But to fail to learn what AIDS is teaching us about topics as diverse as human behavior, sterilization techniques, virology, and medical ethics would be similarly inappropriate. Probably, AIDS will have a greater impact on medical practice than any new disease of recent decades. The numerous clinical problems outlined in this chapter will require constant reevaluation to achieve a safe and prudent health care policy.

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APPENDIX

SUMMARY OF OSHA REGULATIONS

GENERAL

- Employers regulated by the OSH Act are required to comply with the standard if they have any employees who may have "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with potentially infectious materials that may result from the performance of an employee's duties."
- "Potentially infectious materials" include cells, tissue, organs, and bodily fluids that may be infected with "bloodborne pathogens," as well as items that may have come into contact with that type of material.
- "Bloodborne Pathogens" (BP's) are pathogenic microorganisms that are present in human blood and can cause disease in humans. Examples include the human immunodeficiency virus (HIV) which causes AIDS and the hepatitis virus.
- Affected employers are required to:
  - establish a written Exposure Control Plan;
  - institute methods of compliance;
  - provide the Hepatitis B vaccinations;
  - provide post-exposure evaluation and follow-up;
  - establish employee information and training programs;
  - properly label potentially hazardous materials; and
  - comply with record keeping requirements.

EXPOSURE CONTROL PLAN

- Covered employers are required to have a written Exposure Control Plan by ap 6, 1992. The plan must:
  - describe the schedule and method of implementation of the BPS requirements;
  - describe the procedure for evaluation of exposure incidents;
  - list all tasks and procedures that have occupation exposure to BP's.
- The Exposure Control Plan must be reviewed and updated annually and made available to employees and OSHA.

METHODS OF COMPLIANCE

- Covered employers must implement engineering and work practice controls where possible to eliminate or reduce exposure and review them on a regular schedule.
- Covered employers must provide appropriate personal protective equipment at no cost to employees when there may be occupational exposure to BP's and insure that the equipment is properly used and maintained.
- Covered employers must ensure that the worksite is clean and sanitary and that contaminated waste is properly handled.
- Covered employers must make the Hepatitis B vaccine series available at no cost to all employees who are at risk of occupational exposure.
- Covered employers must make a confidential medical evaluation and follow-up immediately available to any employee who has an exposure incident.

- Covered employers must properly label all contaminated material.
- Covered employers must ensure that all employees at risk of occupational exposure participate at least annually in the training program presented by a person knowledgeable in the subject matter.

RECORD KEEPING

- Covered employers are required to keep a record on each employee who experiences occupational exposure. The record must be kept for 30 years after the employee's last employment.
- The record must contain:
  - name and Social Security number;
  - vaccination status;
  - medical evaluations and follow-ups; and
  - training records.

ISSUE DATES

Proposed Rule: 54 FR 23,042 (5/30/89).
Final Rule: 56 FR 64,003 (12/6/91).
Codified: 29 CFT 1910.1030.

IMPLEMENTATION DATES

Effective Date: March 6, 1992
Exposure Control Plan: May 6, 1992
Employee Training: June 6, 1992